Clinical trials appendix
Full-Year and Q4 2017 Results update
The following information about AstraZeneca clinical trials in Phases I-IV has been created with selected information from https://clinicaltrials.gov to facilitate understanding of key aspects of ongoing clinical programmes and is correct to the best of the Company’s knowledge as of 31 December 2017, unless otherwise specified.

It includes estimated timelines with regards to trial completion and first external presentations of primary data. These estimates are subject to change as programmes recruit faster or slower than anticipated and many times are event driven.

Project postings on clinicaltrials.gov are updated on a continuous basis as projects progress. For the most up to date information on our clinical programmes please visit clinicaltrials.gov (https://clinicaltrials.gov)
# List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE</td>
<td>Adverse Event</td>
</tr>
<tr>
<td>AUC</td>
<td>Area Under Curve</td>
</tr>
<tr>
<td>BID</td>
<td>Bis In Die (two times a day)</td>
</tr>
<tr>
<td>CE</td>
<td>Clinically Evaluable</td>
</tr>
<tr>
<td>CMAX</td>
<td>Maximum Concentration Absorbed</td>
</tr>
<tr>
<td>cMITT</td>
<td>Clinical-Modified Intent To Treat</td>
</tr>
<tr>
<td>CNS</td>
<td>Central Nervous System</td>
</tr>
<tr>
<td>DLT</td>
<td>Dose-Limiting Toxicity</td>
</tr>
<tr>
<td>FDC</td>
<td>Fixed-Dose Combination</td>
</tr>
<tr>
<td>FEV</td>
<td>Forced-Expiratory Volume</td>
</tr>
<tr>
<td>FPCD</td>
<td>First Patient Commenced Dosing</td>
</tr>
<tr>
<td>IM</td>
<td>Intra Muscular</td>
</tr>
<tr>
<td>IR</td>
<td>Immediate Release</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>LCM</td>
<td>Lifecycle Management</td>
</tr>
<tr>
<td>LPCD</td>
<td>Last Patient Commenced Dosing</td>
</tr>
<tr>
<td>MAD</td>
<td>Multiple Ascending Dose</td>
</tr>
<tr>
<td>MDI</td>
<td>Metered-Dose Inhaler</td>
</tr>
<tr>
<td>MITT</td>
<td>Modified Intent To Treat</td>
</tr>
<tr>
<td>mMITT</td>
<td>Microbiological-Modified Intent To Treat</td>
</tr>
<tr>
<td>MTD</td>
<td>Maximum Tolerated Dose</td>
</tr>
<tr>
<td>NME</td>
<td>New Molecular Entity</td>
</tr>
<tr>
<td>OLE</td>
<td>Open Long-term Extension</td>
</tr>
<tr>
<td>ORR</td>
<td>Objective Response Rate</td>
</tr>
<tr>
<td>OS</td>
<td>Overall Survival</td>
</tr>
<tr>
<td>PFS</td>
<td>Progression-Free Survival</td>
</tr>
<tr>
<td>PK</td>
<td>Pharmacokinetics</td>
</tr>
<tr>
<td>PD</td>
<td>Pharmacodynamics</td>
</tr>
<tr>
<td>Q2W</td>
<td>Quaque (every) Two Weeks</td>
</tr>
<tr>
<td>Q3W</td>
<td>Quaque (every) Three Weeks</td>
</tr>
<tr>
<td>Q4W</td>
<td>Quaque (every) Four Weeks</td>
</tr>
<tr>
<td>Q8W</td>
<td>Quaque (every) Eight Weeks</td>
</tr>
<tr>
<td>QD</td>
<td>Quaque Die (one time a day)</td>
</tr>
<tr>
<td>SAD</td>
<td>Single Ascending Dose</td>
</tr>
<tr>
<td>SC</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>TID</td>
<td>Ter In Die (three times a day)</td>
</tr>
<tr>
<td>TOC</td>
<td>Test Of Cure</td>
</tr>
<tr>
<td>XR</td>
<td>Extended Release</td>
</tr>
</tbody>
</table>
## Table of contents slide

### Movement since Q3 2017 results announcement
- Year-to-date and Q4 2017 New Molecular Entity (NME) pipeline
- Year-to-date and Q4 2017 Lifecycle Management (LCM) pipeline

### Approved medicines
- Oncology
- Cardiovascular & Metabolic Diseases (CVMD)
- Respiratory
- Other

### Late-stage pipeline
- Oncology
- CVMD
- Respiratory
- Other

### Early development - IMED (AstraZeneca Research & Early Development)
- Oncology
- CVMD
- Respiratory
- Other

### Early development - MedImmune
- Oncology
- CVMD
- Respiratory
- Other
## Movement since Q3 2017 update

<table>
<thead>
<tr>
<th>New to Phase I</th>
<th>New to Phase II</th>
<th>New to Pivotal Study</th>
<th>New to Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD1390</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ATM inhibitor healthy volunteer study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD4573</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDK9 inhibitor hematological malignancies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD5153</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BRD4 inhibitor solid tumours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD9991</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MCL1 inhibitor hematological malignancies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calquence + vistusertib</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BKT inhibitor + mTOR inhibitor hematological malignancies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD1402*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhaled IL-4Ra asthma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Additional indications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infinzi* + tremelimumab + chemo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PD-L1 mAb + CTLA-4 mAb 1st-line PDAC, oesophageal, SCLC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infinzi</td>
<td>RT (platform) CLOVER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PD-L1 mAb + RT locally-advanced HNSCC, NSCLC, SCLC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imfinzi* + MEDI0457*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PD-L1 mAb + DNA HPV vaccine HNSCC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD5718</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FLAP coronary artery disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDI5884*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cholesterol modulation CV disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD9806*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPP1 COPD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD9567</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>oral SGRM rheumatoid arthritis / respiratory</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Additional indications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infinzi* + tremelimumab</td>
<td>PD-L1 mAb + CTLA-4 mAb biliary tract, esophageal</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tezepelumab NAVIGATOR SOURCE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TSLP mAb severe, uncontrolled asthma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Additional indications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infinzi* + tremelimumab</td>
<td>HiMALAYA</td>
<td>PD-L1 mAb + CTLA-4 mAb 1st-line hepatocellular carcinoma</td>
<td></td>
</tr>
<tr>
<td><strong>Life-cycle Management</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brilinta* THALES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P2Y12 receptor antagonist acute ischaemic stroke or transient ischaemic attack</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Removed from Phase I</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDI0680*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PD-1 mAb solid tumours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD9898*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LTC4S asthma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Removed from Phase II</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDI-573*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IGF mAb metastatic breast cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Removed from Phase III</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tralokinumab STRATOS 1, 2 TROPOS MESOS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IL-13 mAb severe, uncontrolled asthma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Removed from Registration</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasenra* (Benralizumab*) CALIMA, SIROCCO [US]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PARP inhibitor gBRCAm breast cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Life-cycle Management</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lynparza* OlympiAD [US]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PARP inhibitor gBRCAm breast cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bydureon BCise [US]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLP-1 receptor agonist type-2 diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Registrational Phase II/III study
+ Partnered and/or in collaboration
1 Submission Accepted 2 Submission Approved 4 Completed
* Brilinta in the US and Japan, Brilique in ROW
# Q4 2017 New Molecular Entity (NME)\(^1\) Pipeline

## Phase I
**34 New Molecular Entities**

<table>
<thead>
<tr>
<th>Small molecule</th>
<th>Large molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZD2199</td>
<td>AZD9311 MPO HIF(\alpha)EF</td>
</tr>
<tr>
<td>AZD1390</td>
<td>AZD8013 VEGF-A cardiovascular</td>
</tr>
<tr>
<td>AZD4158</td>
<td>AZD9258 Inhaled IL-5RA asthma</td>
</tr>
<tr>
<td>AZD9634</td>
<td>AZD8486 Inhaled DN-7C cystic fibrosis</td>
</tr>
<tr>
<td>AZD28190</td>
<td>AZD4780 HER2 solid tumours</td>
</tr>
<tr>
<td>AZD5933</td>
<td>AZD2838 ROS1 protein/RSO1</td>
</tr>
<tr>
<td>AZD2785</td>
<td>AZD7479 RO5105342 actin/retinoic acid</td>
</tr>
<tr>
<td>AZD5135</td>
<td>AZD12410 TERT solid tumours</td>
</tr>
<tr>
<td>AZD5991</td>
<td>AZD22454 LAMA1/EMMT2 copd</td>
</tr>
<tr>
<td>AZD4185</td>
<td>AZD6000 L-33 COPD</td>
</tr>
<tr>
<td>AZD5738</td>
<td>AZD15149 amyloid alzheimer's disease</td>
</tr>
<tr>
<td>AZD5189</td>
<td>AZD7352 WIF1/NF osteoarthritis pain</td>
</tr>
<tr>
<td>AZD4956</td>
<td>AZD7057 SPP1-5L6E</td>
</tr>
<tr>
<td>AZD4605</td>
<td>AZD6220 CD40TN K55</td>
</tr>
<tr>
<td>MED9151</td>
<td>MED7724 LTT myositis</td>
</tr>
<tr>
<td>MED9156</td>
<td>MED9114 LAFI antiic dermatitis</td>
</tr>
</tbody>
</table>

## Phase II
**21 New Molecular Entities**

<table>
<thead>
<tr>
<th>Small molecule</th>
<th>Large molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZD2547</td>
<td>MED1892 CLI G pfase-2 diabetes</td>
</tr>
<tr>
<td>AZD2923</td>
<td>MED8046 cholecalciferol modulation cardiovascular</td>
</tr>
<tr>
<td>AZD3283</td>
<td>MED2047 LYF1 chronic kidney disease</td>
</tr>
<tr>
<td>AZD2671</td>
<td>MED12091 LAMA1/EMMT2 copd</td>
</tr>
<tr>
<td>AZD6003</td>
<td>MED9282 LAMA1/EMMT2 copd</td>
</tr>
<tr>
<td>AZD6508</td>
<td>MED9102 Paclitaxel/Mitoxantrone</td>
</tr>
<tr>
<td>AZD3418</td>
<td>MED852 Influenza A treatment</td>
</tr>
<tr>
<td>AZD2693</td>
<td>MED8074 passive RSV prophylaxis</td>
</tr>
<tr>
<td>AZD9977</td>
<td>MED4893 sebinol (MED4903)</td>
</tr>
</tbody>
</table>

## Phase III
**9 New Molecular Entities**

<table>
<thead>
<tr>
<th>Small molecule</th>
<th>Large molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZD3578</td>
<td>MED19558 BTLX-000011</td>
</tr>
<tr>
<td>AZD3579</td>
<td>MED9022701 Daptomycin BM140942</td>
</tr>
<tr>
<td>AZD3809</td>
<td>MED48942 SEB-150101</td>
</tr>
<tr>
<td>AZD3580</td>
<td>MED48942 SEB-150101</td>
</tr>
<tr>
<td>AZD3581</td>
<td>MED48942 SEB-150101</td>
</tr>
<tr>
<td>AZD3582</td>
<td>MED48942 SEB-150101</td>
</tr>
<tr>
<td>AZD3583</td>
<td>MED48942 SEB-150101</td>
</tr>
<tr>
<td>AZD3584</td>
<td>MED48942 SEB-150101</td>
</tr>
<tr>
<td>AZD3585</td>
<td>MED48942 SEB-150101</td>
</tr>
</tbody>
</table>

## Applications Under Review
**2 New Molecular Entities**

<table>
<thead>
<tr>
<th>Small molecule</th>
<th>Large molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZD3578</td>
<td>MED19558 BTLX-000011</td>
</tr>
<tr>
<td>AZD3579</td>
<td>MED48942 SEB-150101</td>
</tr>
</tbody>
</table>

---

\(^1\) Includes significant fixed-dose combination projects, and parallel indications that are in a separate therapy area (See LCM chart for other parallel indications and oncology combination projects)

\# Partnered and/or in collaboration,\(^1\) Registrational P2/3 study
Q4 2017 Lifecycle Management (LCM) Pipeline

**Phase I**
- 0 Projects

**Phase II**
- 7 Projects
  - Small molecule
    - Tagrisso BLOOM EGFR NSCLC CNS mets
    - Lynparza HESTIA P2Y12 plaques w/ stable cell
    - Ixazomib Type I FN receptor SLE SC
  - Large molecule
    - PD-L1 sold tumors
    - TSLP atopic dermatitis
    - IFN LABALAMICS asthma

**Phase III**
- 22 Projects
  - Small molecule
    - Calquence BTK inhibitor 1st line MCL
    - Calquence BTK inhibitor 1st line CLL
    - Lynparza Olympia PARP gynecologic ovarian / breast
    - Lynparza POLO PARP pancreatic cancer
    - Lynparza PROsound PARP prostate cancer
    - Lynparza SOL0-1 PARP 1L BRCA1 ovarian
    - Lynparza SOL0-3 PARP BRCA1/2 ovarian
    - Tagrisso ADAMIA EGFR m on EGFRT NSCLC
    - Tagrisso FLAURA EGFR 2nd adv. EGFRT NSCLC
  - Large molecule
    - Darvium/Eructive HALOED P2Y12 stroke
    - Darvium/Eructive THEMES P2Y12 diabetes & CAD outcomes
    - Lynparza/verteporfin STRATEGIST outcomes
    - Eprinomys LAMICEL outcomes
    - Fazzanr (nonalzamit) IL-5R COPD

**Applications Under Review**
- 3 Projects
  - Small molecule
    - Infinius# PACIFIC PD-L1 stage 3 NSCLC
    - Vasculard (CN only) stress ulcer prophylaxis
  - Large molecule
    - Infinius# PACIFIC PD-L1 stage 3 NSCLC

---

1 Includes significant LCM projects and parallel indications for assets in P3 or beyond. Excludes LCM projects already launched in a major market.

# Partnered and/or in collaboration; ¹ Registrational P2/3 study.
Q4 2017 Lifecycle Management (LCM)\(^1\) Pipeline

\(^1\) Includes significant LCM projects and parallel indications for assets in P3 or beyond. Excludes LCM projects already launched in a major market

# Partnered and/or in collaboration; \(^\#\) Registrational P2/3 study
Approved medicines
# Lynparza (PARP inhibitor)

## Ovarian cancer and other cancers

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III</strong></td>
<td><strong>SOLO-2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| NCT01874353    | Platinum-sensitive recurrent (PSR) BRCAm ovarian cancer | 295      | • Arm 1: Lynparza tablets 300mg BID as maintenance therapy until progression  
              |                                               |          | • Arm 2: placebo tablets BID                                           | • Primary endpoint: PFS             | FPCD: Q3 2013                       |
|                |                                         |          |                                                                       | • Secondary endpoint: OS                       |                                    |
|                |                                         |          |                                                                       |                                               |                                    |
| **Phase III**  | **SOLO-1**                              |          |                                                                       |                                               |                                    |
| NCT01844986    | 1L maintenance BRCAm ovarian cancer      | 391      | • Arm 1: Lynparza tablets 300mg BID maintenance therapy for 2 years or until disease progression  
              |                                               |          | • Arm 2: placebo                                                       | • Primary endpoint: PFS             | FPCD: Q3 2013                       |
|                |                                         |          |                                                                       | • Secondary endpoint: OS                       |                                    |
|                |                                         |          |                                                                       |                                               |                                    |
| **Phase III**  | **SOLO-3**                              |          |                                                                       |                                               |                                    |
| NCT02282020    | PSR gBRCAm ovarian cancer 3L+ Line       | 411      | • Arm 1: Lynparza 300mg BID to progression                              |
|                |                                         |          | • Arm 2: Physician’s choice (single agent chemotherapy)                | • Primary endpoint: PFS                       | FPCD: Q1 2015                       |
|                |                                         |          |                                                                       | • Secondary endpoint: OS                       |                                    |
|                |                                         |          |                                                                       |                                               |                                    |
| **Phase I / II**| **MEDIOLA**                             |          |                                                                       |                                               |                                    |
| NCT02734004    | gBRCAm ovarian cancer 2L+                 | 133      | • Arm 1: Lynparza tablets 300mg BID starting on week 1 day 1 / Imfinzi IV 1.5g every 4 weeks starting on week 5 day 1  
              |                                               |          | • Dose until progression                                               | Primary endpoints                 | FPCD: Q2 2016                       |
|                | gBRCAm HER2-negative breast cancer 1-3L  |          |                                                                       | • Disease control rate (DCR) at 12 weeks       |                                    |
|                | Small cell lung cancer (SCLC) 2L+        |          |                                                                       | • Safety and tolerability                      |                                    |
|                | Gastric cancer 2L+                       |          |                                                                       | Secondary endpoints                           |                                    |
|                |                                         |          |                                                                       | • DCR at 28 weeks                              |                                    |
|                |                                         |          |                                                                       | • ORR, duration of response (DoR), PFS, TDT, OS |                                    |
|                |                                         |          |                                                                       | • PK                                           |                                    |
| PARP = Poly ADP Ribose Polymerase |                                      |          |                                                                       |                                               |                                    |
# Lynparza (PARP inhibitor)

## Breast cancer and other cancers

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III OlympiAD**  NCT02000622 | BRCAm metastatic breast cancer | 302 | • Arm 1: Lynparza 300mg BID, continuous to progression  
• Arm 2: Physician’s choice: capcitabine 2500mg/m² x 14 q 21  
vinorelbine 30mg/m² d 1, 8 q 21  
eribulin 1.4mg/m² d 1, 8 q 21 to progression  
Global trial | • Primary endpoint: PFS  
• Secondary endpoint: OS | • FPED: Q2 2014  
• LPCD: Q4 2015  
• Data readout: Q1 2017  
• Primary endpoint met |
| **Phase III OlympiA**  NCT02032823 Partnered | BRCAm adjuvant breast cancer | 1,500 | • Arm 1: Lynparza 300mg BID  
12 month duration  
• Arm 2: Placebo 12 month duration  
Global trial partnership with BIG and NCI/NCRG | • Primary endpoint: invasive disease-free survival (IDFS)  
• Secondary endpoint: distant disease-free survival and OS | • FPED: Q2 2014 |
| **Phase III POLO**  NCT02184195 | gBRCAm pancreatic cancer | 145 | • Arm 1: Lynparza tablets 300mg twice daily as maintenance therapy until progression  
• Arm 2: Placebo tablets BID | • Primary endpoint: PFS  
• Secondary endpoint: OS | • FPED: Q1 2015 |
| **Phase II**  NCT01972217 | Metastatic castration resistant prostate cancer | 142 | • Arm 1: Lynparza 300mg BID + abiraterone  
• Arm 2: Placebo + abiraterone  
Global trial | • Primary endpoint: Radiologic PFS | • FPED: Q3 2014  
• LPCD: Q3 2015  
• Data readout: Q4 2017 |
| **Phase III PROfound**  NCT0287543 | Metastatic castration resistant prostate cancer  
HRRm, 2L+ | 340 | • Arm 1: Lynparza 300mg BID  
• Arm 2: Physician’s choice: enzalutamide 160mg once daily  
abiraterone acetate 1000mg once daily  
Global trial | • Primary endpoint: Radiologic PFS  
• Secondary endpoints: ORR, Time to Pain Progression, OS | • FPED: Q2 2017 |

PARP = Poly ADP Ribose Polymerase  
HRRm – Homologous recombination repair mutation
# Tagrisso (Highly-selective, irreversible EGFRi)

Non-small cell lung cancer (NSCLC)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III AURA3 NCT02151981 | Advanced EGFRm NSCLC Tyrosine kinase inhibitor (TKI) failure and primary resistance mutation T790M | 410 | Arm 1: Tagrisso 80mg QD  
Arm 2: pemetrexed 500mg/m² + carboplatin AUC5 or pemetrexed 500mg/m² + cisplatin 75mg/m² (2:1 randomisation)  
Global trial – 18 countries | Primary endpoint: PFS  
Secondary endpoints: OS and quality of life (QoL) | FPCD: Q3 2014  
Data readout: Q3 2016  
Primary endpoint met |
| Phase III FLAURA NCT02296125 | Advanced EGFRm NSCLC 1L | 556 | Arm 1: Tagrisso 80mg  
Arm 2: erlotinib 150mg or ± rixsa 250mg (physicians choice); 1:1 randomisation  
Global trial – 30 countries | Primary endpoint: PFS  
Secondary endpoints: OS and QoL | FPCD: Q1 2015  
LPCD: Q4 2016  
Data readout: Q3 2017  
Primary endpoint met |
| Phase III ADAURA NCT02511106 | Adjuvant EGFRm NSCLC | 700 | Arm 1: Tagrisso 80mg QD following complete tumour resection, with or without chemotherapy  
Arm 2: Placebo  
Global trial – 25 countries | Primary endpoint: Disease Free Survival (DFS)  
Secondary endpoints: DFS Rate, OS, OS Rate, QoL | FPCD: Q4 2015  
Data anticipated: 2022 |
| Phase II AURA17 NCT02442349 | Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M | 171 | Tagrisso 80mg QD  
Asia-Pacific regional trial – 3 countries | Primary endpoint: ORR  
Secondary endpoints: PFS and OS | FPCD: Q3 2015  
Data readout: Q2 2016 |
| Phase II AURA2 NCT02094261 | Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M | 210 | Tagrisso 80mg QD  
Global trial - 8 countries | Primary endpoint: ORR  
Secondary endpoints: PFS and DoR | FPCD: Q2 2014  
LPCD: Q4 2014 |
| Phase III AURA NCT01802632 | Advanced EGFRm NSCLC TKI failure +/- primary resistance mutation T790M | 603 | Dose escalation trial  
Ph II Extension cohort (T790M only) Tagrisso 80mg QD  
Global trial – 10 countries | Primary endpoint: ORR  
Secondary endpoints: PFS and OS | FPCD: Q1 2013  
LPCD: Q4 2014 |
### Tagrisso (Highly-selective, irreversible EGFRi)

Non-small cell lung cancer (NSCLC)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase Ib       | Advanced EGFRm NSCLC TKI failure                 | 308      | • Arm 1: Tagrisso + Imfinzi  
• Arm 2: Tagrisso + savolitinib  
• Arm 3: Tagrisso + selumetinib  
Global trial | • Safety, Tolerability, Pharmacokinetics and Preliminary anti-tumour Activity | • FPCD: Q3 2014  
• Enrolment to Imfinzi combination arms will not restart |
| TATTON NCT02143466 |                                                  |          |                                                                        |                                                                           |                                                                        |
| Phase I        | EGFRm NSCLC, central nervous system (CNS) disease | 108      | • Maximal administered dose (MAD)  
• Expansion in leptomeningeal metastasis (LM) and brain metastasis (BM) patients at RP2D with AZD3759  
• Expansion in LM patients at 160mg with Tagrisso including cohort with T790M NSCLC  
Global trial – four countries | • Safety and tolerability  
• Preliminary anti-tumour activity | • FPCD: Q4 2014  
• Data readout: Q2 2017 |
| BLOOM NCT02228369 |                                                  |          |                                                                        |                                                                           |                                                                        |
| Phase III      | Real world setting in adult patients with advanced or metastatic, EGFR T790M+ NSCLC | 3,515    | Single arm study - Tagrisso 80mg  
Global trial – 16 countries | • Primary endpoints: OS and Safety  
• Secondary endpoint: PFS | • FPCD: Q3 2015 |
| ASTRIS NCT02474355 |                                                  |          |                                                                        |                                                                           |                                                                        |
# Imfinzi (PD-L1 mAb)

## Non-small cell lung cancer (NSCLC)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Phase</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III ADJUVANT**  
NCT02273375  
Partnered | **ADJUVANT** | Adjuvant NSCLC patients IB (≥4cm) – IIA resected NSCLC (incl. EGFR/ALK positive)  
1,100 | • Arm 1: Imfinzi mg/kg IV Q4W x 12m  
• Arm 2: Placebo  
Global trial  
• Primary endpoint: DFS  
• Secondary endpoint: OS | • FP CD: Q1 2015  
• Data anticipated: 2021 |
| **Phase III PACIFIC**  
NCT02125461  
Partnered | **PACIFIC** | Unresectable NSCLC patients following platinum-based concurrent chemo-radiation therapy  
702 | • Arm 1: Imfinzi IV Q2W  
• Arm 2: Placebo  
Global trial  
• Primary endpoints:  
  • PFS  
  • OS | • FP CD: Q2 2014  
• LPCD: Q2 2016  
• Data readout: Q2 2017  
• Primary endpoint met |
| **Phase III Lung Master Protocol**  
NCT02154490  
Partnered | **Lung Master Protocol** | Stage IV squamous NSCLC patients  
Biomarker-targeted 2L therapy  
140 ; 100 Imfinzi treated  
Umbrella trial with five arms based on biomarker expression  
  - Substudy A: Imfinzi (non-match for other biomarker driven substudies) IVQ2W single arm Imfinzi Phill only  
  - Substudy B: PI3K inhibitor vs docetaxel  
  - Substudy C: CDK4/6 inhibitor vs docetaxel  
  - Substudy D: AZD4547 (FGFR inhibitor) vs docetaxel  
  - Substudy E: C-MET/HGF Inhibitor + erlotinib vs erlotinib (Substudy is closed)  
Global trial  
• Primary endpoints:  
  • ORR  
  • PFS  
  • OS | • FP CD: Q2 2014  
• Data anticipated: 2022 |
| **Phase II ATLANTIC**  
NCT02087423  
Partnered | **ATLANTIC** | Stage IIIB-IV NSCLC patients  
PD-L1+ve patients  
3L  
293 | • Arm 1: Imfinzi IV Q2W (EGFR/ALK WT)  
• Arm 2: imfinzi IV Q2W (EGFR/ALK M+)  
• Arm 3: Imfinzi IV Q2W (EGFR/ALK WT) (90% PD-L1 - expression)  
Global trial  
  – 18 countries | • Primary endpoint: ORR  
• Secondary endpoints: DoR, PFS and OS  
• FP CD: Q1 2014  
• LPCD: Q2 2015  
• Data readout: Q4 2015 |
| **Phase VII Sequencing Study**  
NCT02179671  
Partnered | **Sequencing Study** | Stage IIIB-IV NSCLC patients  
72 | • Arm 1: Iressa initially then switch to Imfinzi IVQ2W  
• Arm 2: AZD0291 then switch to Imfinzi  
• Arm 3: selumetinib + docetaxel then switch to Imfinzi  
• Arm 4: tremelimumab then switch to Imfinzi  
Global trial  
• Primary endpoint: Complete Response Rate  
• Secondary endpoints: ORR, Disease Control Rate | • FP CD: Q3 2014  
• LPCD: Q2 2016  
• Data readout: Q2 2016 |
| **Phase III PEARL**  
NCT03003962  
Partnered | **PEARL** | NSCLC 1L  
440 | • Arm 1 Imfinzi Q4W  
• Arm 2 Chemotherapy (SoC)  
Asia trial | Primary endpoints:  
  • PFS  
  • OS  
• FP CD: Q1 2017  
• Data anticipated: 2020 |
**Imfinzi (PD-L1 mAb)**

**Other cancers**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Solid tumours</td>
<td>108</td>
<td>• Dose Escalation: N=36, three cohorts receiving Treatment A (mogamulizumab + Imfinzi) and three cohorts receiving Treatment B (mogamulizumab + treme), in parallel&lt;br&gt;• Dose Expansion: N=72, Multiple solid tumour types (NSCLC, HNSCC, Pancreatic), Treatment A or B (12 subjects per treatment per disease type, in parallel)</td>
<td>• Safety and Tolerability&lt;br&gt;• MTD&lt;br&gt;• ORR, DoR, DCR, PFS, OS</td>
<td>FPCD: Q4 2014&lt;br&gt;LPCD: Q3 2017&lt;br&gt;Data anticipated: 2018</td>
</tr>
<tr>
<td>NCT02301130</td>
<td>Partnered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>Solid tumours (all-comers)</td>
<td>176</td>
<td>• Dose Escalation: 3 cohorts at Q2W and 1 cohort at Q3W&lt;br&gt;• Dose Expansion: Biliary Tract Cancer, Oesophageal Cancer and SCCHN, Q2, and Q4 schedule&lt;br&gt;• Dose Expansion of combination: Biliary Tract Cancer and Oesophageal Cancer, Imfinzi Q4W 20mg/kg + tremelimumab Q4W 1mg/kg&lt;br&gt;Trial conducted in Japan</td>
<td>• Safety&lt;br&gt;• Optimal biologic dose</td>
<td>FPCD: Q3 2013&lt;br&gt;LPCD: Q1 2017&lt;br&gt;Data anticipated: 2018</td>
</tr>
<tr>
<td>NCT01938612</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Imfinzi (PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

#### Non-small cell lung cancer (NSCLC) and other cancers

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III ARCTIC NCT02352948 | Stage IIIB-IV NSCLC patients who have not been tested positive for EGFR/ALK mutation | 480 | • Arm 1: Imfinzi + tremelimumab (PD-L1–ve patients)  
• Arm 2: Standard of care  
• Arm 3: tremelimumab (PD-L1–ve patients)  
• Arm 4: Imfinzi (PD-L1–ve patients) | Primary endpoints:  
• PFS  
• OS | • FPCD: Q2 2015  
• LPCD: Q3 2016  
• Data anticipated: H1 2018 |
| Phase III MYSTIC NCT02453282 | NSCLC 1L | 1,118 | • Arm 1: Imfinzi  
• Arm 2: Imfinzi + tremelimumab  
• Arm 3: Standard of care | Primary endpoints:  
• PFS  
• OS | • FPCD: Q3 2015  
• LPCD: Q3 2016  
• Data anticipated: H1 2018 (OS)  
• PFS Primary endpoint not met |
| Phase III NEPTUNE NCT02542293 | NSCLC 1L | 960 | • Arm 1: Imfinzi + tremelimumab  
• Arm 2: Standard of care | Primary endpoint: OS  
Secondary endpoint: PFS | • FPCD: Q4 2015  
• LPCD: Q2 2017  
• Data anticipated: H2 2018 |
| Phase III POSEIDON NCT03164616 | NSCLC 1L | 801 | • Arm 1: Imfinzi + CTx  
• Arm 2: Imfinzi + tremelimumab + chemotherapy  
• Arm 3: chemotherapy | Primary endpoints:  
• PFS | • FPCD: Q2 2017  
• Data anticipated: 2019 |
| Phase III EAGLE NCT02369874 | HNSCC 2L | 736 | • Arm 1: Imfinzi + tremelimumab  
• Arm 2: Imfinzi  
• Arm 3: Standard of care | Primary endpoint: OS  
Secondary endpoint: PFS | • FPCD: Q4 2015  
• LPCD: Q3 2017  
• Data anticipated: H1 2018 |
| Phase III KESTREL NCT02551159 | HNSCC 1L | 823 | • Arm 1: Imfinzi  
• Arm 2: Imfinzi + tremelimumab  
• Arm 3: Standard of care | Primary endpoints:  
• PFS  
• OS | • FPCD: Q4 2015  
• LPCD Q1 2017  
• Data anticipated: H1 2018 |
| Phase III DANUBE NCT02516241 | Bladder 1L cis eligible and ineligible | 1,005 | • Arm 1: Imfinzi + tremelimumab  
• Arm 2: Imfinzi  
• Arm 3: Standard of care | Primary endpoints:  
• OS | • FPCD: Q4 2015  
• LPCD Q1 2017  
• Data anticipated: H1 2018 |
| Phase III CASPIAN NCT03043872 | SCLC 1L | 795 | • Arm 1: Imfinzi + tremelimumab + EP (carboplatin or cisplatin + etoposide)  
• Arm 2: Imfinzi + EP (carboplatin or cisplatin + etoposide)  
• Arm 3: Imfinzi + EP (carboplatin or cisplatin + etoposide) | Primary endpoints:  
• PFS  
• OS | • FPCD: Q1 2017  
• Data anticipated: 2019 |
# Imfinzi (PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

## Other cancers

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| STRONG | Advanced Solid Malignancies | 1,200 | • Arm 1: Imfinzi  
• Arm 2: Imfinzi + tremelimumab | • Primary endpoint: Safety | • FPCD: Q2 2017  
• Data anticipated: 2022 |
| NCT03084471 | | | | | |
| **Phase II** | | | | | |
| BALTIC | Urothelial Bladder Cancer  
Triple-negative Breast Cancer  
Pancreatic Ductal-Adenocarcinoma | 76 | • Arm 1 tremelimumab in urothelial bladder cancer  
• Arm 2 tremelimumab triple-negative breast cancer  
• Arm 3 tremelimumab pancreatic ductal-adenocarcinoma | • Primary endpoint: ORR  
Secondary endpoints:  
• Safety  
• DoR | • FPCD: Q4 2016  
• Data Anticipated: 2020 |
| NCT02527434 | | | | | |
| **Phase I Combination in Advanced Solid Tumours** | | | | | |
| NCT02658214 | Solid tumours | 80 | • Arm 2 SCLC: Imfinzi + tremelimumab + carboplatin + etoposide  
• Arm 3 TNBC: Imfinzi+ tremelimumab + gemcitabine + carboplatin  
• Arm 4 TNBC: Imfinzi + tremelimumab + nab-paclitaxel (paclitaxel-albumin) + carboplatin  
• Arm 5 Gastric/Gastro-Oesophageal junction (GEJ): Imfinzi + tremelimumab + oxaliplatin + 5-fluorouracil (5FU) + leucovorin (calcium folinate/folinic acid)  
• Arm 6 PDAC: Imfinzi+ tremelimumab + nab-paclitaxel (paclitaxel-albumin) + gemcitabine  
• Arm 7 ESSC: Imfinzi+ tremelimumab + cisplatin + 5-fluorouracil (5FU) | • Safety | • FPCD: Q1 2016  
• LPCD: Q4 2016  
• Data anticipated: 2019 |
| **Phase III** | | | | | |
| HIMALAYA | Unresectable Hepatocellular Carcinoma | 1,200 | • Arm 1: Imfinzi + tremelimumab (Regimen 1)  
• Arm 2: Imfinzi + tremelimumab (Regimen 2)  
• Arm 3: Imfinzi  
• Arm 4: sorafenib | • Primary endpoint: OS  
Secondary endpoint: PFS, time to tumour progression (TTP), ORR | • Data anticipated: 2020 |
## Calquence (acalabrutinib, BTK inhibitor)

### Blood cancers

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoint(s)</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III ACE-CL-006 (ELEVATE-RR) NCT02477696 | Relapsed/refractory chronic lymphocytic leukaemia (CLL), high risk | 500 | Arm A: Calquence  
Arm B: ibritinib | Primary endpoint: PFS  
Secondary endpoints: comparison of incidence of infections, RTs and atrial fibrillation, OS | FPCD: Q2 2015  
Data anticipated: 2019 |
| Phase III ACE-CL-007 (ELEVATE-TN) NCT02475681 | Previously untreated CLL | 535 | Arm A: chlorambucil + obinutuzumab  
Arm B: Calquence + obinutuzumab  
Arm C: Calquence | Primary endpoint: PFS (Arm A vs Arm B)  
Secondary endpoints: IRC assessed ORR, TTNT, OS (Arm A vs Arm B vs Arm C) | FPCD: Q2 2015  
Data anticipated: 2019 |
| Phase III ACE-CL-309 NCT02970318 | Relapsed/refractory CLL | 306 | Arm A: Calquence  
Arm B: rituximab + idealisib or bendamustine (investigator’s choice) | Primary endpoint: IRC assessed PFS  
Secondary endpoints: INV assessed ORR, TTNT, OS, DOR, PROs | FPCD Q3 2016  
Data anticipated: 2020 |
| Phase III ACE-LY-004 NCT02213926 | Relapsed/refractory MCL | 124 | Calquence monotherapy | ORR | FPCD: Q3 2014  
Data readout: Q4 2017 |
| Phase II ACE-CL-001 NCT02029443 | CLL/SLL/Richter's transformation (RT) | 286 | Calquence monotherapy  
Dose escalation and expansion | Safety, PK, PD  
Secondary endpoints: ORR, DOR, and PFS | FPCD: Q1 2014  
LPCD: Q2 2016  
Data anticipated: 2019 |
# Calquence (acalabrutinib, BTK inhibitor)

## Blood cancers

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoint(s)</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III&lt;br&gt;ACE-LY-001&lt;br&gt;NCT02328014</td>
<td>B-Cell Malignancies</td>
<td>126</td>
<td>Dose escalation and expansion trial of the combination of Calquence and ACP-319 (PI3K inhibitor)</td>
<td>• Safety&lt;br&gt;• ORR</td>
<td>• FPCD: Q4 2014&lt;br&gt;• Data readout: Q4 2017</td>
</tr>
<tr>
<td>Phase III&lt;br&gt;ACE-LY-005&lt;br&gt;NCT02362035</td>
<td>Haematological Malignancies</td>
<td>159</td>
<td>Calquence + pembrolizumab</td>
<td>• Safety&lt;br&gt;• Secondary endpoints: ORR, DOR, PFS, OS, TTNT</td>
<td>• FPCD: Q1 2015&lt;br&gt;• Data anticipated: 2021</td>
</tr>
<tr>
<td>Phase III&lt;br&gt;ACE-WM-001&lt;br&gt;NCT02180724</td>
<td>Waldenström Microglobulinaemia (WM)</td>
<td>106</td>
<td>Calquence monotherapy</td>
<td>• ORR</td>
<td>• FPCD: Q3 2014&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Data readout: Q2 2020</td>
</tr>
<tr>
<td>Phase Ib&lt;br&gt;ACE-LY-002&lt;br&gt;NCT02112526</td>
<td>Relapsed/refractory de novo ABC Diffuse large B-cell lymphoma (DLBCL)</td>
<td>21</td>
<td>Calquence monotherapy</td>
<td>• Safety</td>
<td>• FPCD: Q3 2014&lt;br&gt;• LPCD: Q2 2016&lt;br&gt;• Data readout: Q2 2017</td>
</tr>
<tr>
<td>Phase Ib&lt;br&gt;ACE-LY-106&lt;br&gt;NCT02717624</td>
<td>Mantle Cell Lymphoma (MCL)</td>
<td>48</td>
<td>Calquence in combination with bendamustine and rituximab&lt;br&gt;• Arm A: Treatment naive&lt;br&gt;• Arm B: Relapsed/refractory</td>
<td>• Safety</td>
<td>• FPCD: Q1 2016&lt;br&gt;• Data anticipated: 2021</td>
</tr>
<tr>
<td>Phase Ib&lt;br&gt;ACE-MY-001&lt;br&gt;NCT02211014</td>
<td>Relapsed/refractory Multiple Myeloma</td>
<td>28</td>
<td>• Arm A: Calquence&lt;br&gt;• Arm B: Calquence + dexamethasone</td>
<td>• Safety</td>
<td>• FPCD: Q1 2015&lt;br&gt;• LPCD: Q1 2016&lt;br&gt;• Data readout: Q2 2017</td>
</tr>
<tr>
<td>Phase I&lt;br&gt;ACE-LY-003&lt;br&gt;NCT02180711</td>
<td>Relapsed/refractory Follicular Lymphoma</td>
<td>40</td>
<td>• Arm A: Calquence&lt;br&gt;• Arm B: Calquence + rituximab</td>
<td>• Safety</td>
<td>• FPCD: Q3 2014&lt;br&gt;• LPCD: Q3 2016&lt;br&gt;• Data anticipated: 2022</td>
</tr>
<tr>
<td>Phase I&lt;br&gt;ACE-CL-002&lt;br&gt;NCT02157324</td>
<td>Relapsed/refractory CLL/SLL</td>
<td>12</td>
<td>Calquence in combination with ACP-319 Dose escalation</td>
<td>• Safety, PK, PD</td>
<td>• FPCD: Q3 2014&lt;br&gt;• LPCD: Q3 2015&lt;br&gt;• Data anticipated: 2016</td>
</tr>
<tr>
<td>Phase I&lt;br&gt;ACE-CL-003&lt;br&gt;NCT02296918</td>
<td>CLL/SLL/Prolymphocytic leukaemia (PLL)</td>
<td>45</td>
<td>Calquence + obinutuzumab&lt;br&gt;• Arm A: Relapsed/refractory&lt;br&gt;• Arm B: Treatment naive</td>
<td>• Safety, ORR&lt;br&gt;• Secondary endpoints: PD, PFS, TTN, OS</td>
<td>• FPCD: Q4 2014&lt;br&gt;• LPCD: Q1 2018&lt;br&gt;• Data anticipated: 2022</td>
</tr>
</tbody>
</table>
**Calquence (acalabrutinib, BTK inhibitor)**

**Blood cancers**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoint(s)</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I | Japanese Adults with Advanced B-cell Malignancies | 28       | • Calquence monotherapy  
• Dose confirmation and expansion | • Safety                                          | • FPCD: Q2 2017  
• Data anticipated: 2021                        |
| NCT03198650 |                                                  |          |                                                                      |                                                 |                                             |
| Phase II| R/R B-cell Malignancies                         | 59       | • Arm A: Calquence daily + vistusertib daily  
• Arm B: Calquence daily + vistusertib 5 days on and 2 days off | • Identify dose and schedule for vistusertib  
• Safety of coadministration of acalabrutinib + vistusertib | • FPCD: Q3 2017  
• Data anticipated: 2019                        |
| NCT03205046 |                                                  |          |                                                                      |                                                 |                                             |
### Calquence (acalabrutinib, BTK inhibitor)

#### Other cancers

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoint(s)</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II ACE-ST-006 NCT02454179 | ≥ 2L advanced or metastatic HNSCC | 74 | • Arm A: pembrolizumab  
• Arm B: Calquence + pembrolizumab | • ORR | • FPCD: Q2 2015  
• LPCD: Q2 2016  
• Data readout: Q4 2017 |
| Phase II ACE-ST-007 NCT02448303 | ≥ 2L advanced or metastatic NSCLC | 74 | • Arm A: pembrolizumab  
• Arm B: Calquence + pembrolizumab | • ORR | • FPCD: Q2 2015  
• LPCD Q2 2016  
• Data readout: Q2 2017 |
| Phase II ACE-ST-208 NCT02537444 | Recurrent ovarian cancer | 76 | • Arm A: Calquence  
• Arm B: Calquence + pembrolizumab | • ORR | • FPCD: Q4 2015  
• LPCD Q2 2016  
• Data readout: Q4 2017 |
| Phase II ACE-ST-003 NCT02362048 | ≥ 2L advanced or metastatic pancreatic cancer | 73 | • Arm A: Calquence  
• Arm B: Calquence + pembrolizumab | • Safety | • FPCD: Q2 2015  
• LPCD: Q1 2016  
• Data readout: Q2 2017 |
| Phase II ACE-ST-005 NCT02351739 | Platinum-resistant urothelial bladder cancer | 75 | • Arm A: pembrolizumab  
• Arm B: Calquence + pembrolizumab | • ORR | • FPCD: Q2 2015  
• LPCD: Q1 2016  
• Data readout: Q4 2017 |
| Phase IIb/III ACE-ST-209 NCT02586857 | ≥ 2L glioblastoma multiforme | 72 | • Arm A: Calquence 200 mg BID  
• Arm B: Calquence 400 mg QD | • Safety, ORR  
• Secondary Endpoints: DOR, PFS, PFS-6, OS | • FPCD: Q1 2016  
• Data anticipated: H1 2018 |
# Brilinta (ADP receptor antagonist)

## Cardiovascular risk reduction

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints (primary)</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III THEMIS | Patients with type-2 diabetes and coronary artery disease without a previous history of myocardial infarction (MI) or stroke | 19,000   | Arm 1: Brilinta 60mg BID  
Arm 2: Placebo BID on a background of acetylsalicylic acid if not contra-indicated or not tolerated  
Global trial – 42 countries | Primary endpoint: Composite of cardiovascular (CV) death, non-fatal MI and non-fatal stroke  
Secondary endpoints:  
Prevention of CV death  
Prevention of MI  
Prevention of ischaemic stroke  
Prevention of all-cause death | FP CD: Q1 2014  
LP CD: Q2 2016  
Data anticipated: 2019 |
| Phase III THALES | Patients with Acute Ischaemic Stroke or Transient Ischaemic Attack | 13,000   | Arm 1: Brilinta 60mg BID  
Arm 2: Placebo BID on a background of acetylsalicylic acid if not contra-indicated or not tolerated  
Global trial – 28 countries | Primary endpoint: Prevention of the composite of subsequent stroke and death at 30 days  
Secondary endpoints include:  
Prevention of subsequent ischaemic stroke at 30 days  
Reduction of overall disability at 30 days | FP CD: Q1 2018  
Data anticipated: 2020 |
# Farxiga (SGLT2 inhibitor)

## Diabetes

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III/IV   | Type-2 diabetes with high risk for CV event                                 | 17,276   | • Arm 1: Farxiga 10mg QD + SoC therapy QD  
• Arm 2: Placebo + SoC therapy for type-2 Diabetes  
Global trial – 33 countries                                                                 | • Primary endpoint: Time to first event included in the composite endpoint of CV death, MI or ischaemic stroke | • FPCD: Q2 2013  
• Data anticipated: H2 2018 |
| DECLARE        |                                                                            | NCT01730534 |                                                                  |                                                                                                                                         |                                                                      |
| Phase III      | Asian patients with type-2 diabetes with inadequate glycemic control on insulin | 273      | • Arm 1: Farxiga 10mg QD for 24 weeks + background insulin  
• Arm 2: Placebo QD for 24 weeks + background insulin  
Asia trial – three countries                                                                 | • Primary endpoint: Change from baseline in Haemoglobin A1C (HbA1c) at week 24 | • FPCD: Q1 2014  
• LPCD: Q1 2016  
• Data Readout: Q2 2016  
• Primary endpoint met |
| DERIVE         | Patients with type-2 diabetes and moderate renal impairment                | 302      | • Arm 1: Farxiga 10mg QD for 24 weeks  
• Arm 2: Placebo 10mg QD for 24 weeks  
Global trial – eight countries                                                                 | • Primary endpoint: Change from baseline in HbA1c at week 24 | • FPCD: Q2 2015  
• LPCD: Q2 2017 |
| Phase III      |                                                                            | NCT02413398 |                                                                  |                                                                                                                                         |                                                                      |
| Phase III      | Type-1 diabetes                                                            | 768      | • Arm 1: Farxiga 5mg QD 52 weeks + insulin  
• Arm 2: Farxiga 10mg QD 52 weeks + insulin  
• Arm 3: Placebo QD 52 weeks + insulin  
Global trial – 17 countries                                                                 | • Primary endpoint: Adjusted Mean Change From Baseline in HbA1c at week 24 | • FPCD: Q4 2014  
• LPCD Q2 2016  
• Data readout: Q1 2017 |
| DEPICT 1       |                                                                            | NCT02268214 |                                                                  |                                                                                                                                         |                                                                      |
| Phase III      | Type-1 diabetes                                                            | 768      | • Arm 1: Farxiga 5mg QD 52 weeks + insulin  
• Arm 2: Farxiga 10mg QD 52 weeks + insulin  
• Arm 3: Placebo QD 52 weeks + insulin  
Global trial – 14 countries                                                                 | • Primary endpoint: Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at week 24 | • FPCD: Q3 2015  
• LPCD: Q1 2017 |
| DEPICT 2       |                                                                            | NCT02460978 |                                                                  |                                                                                                                                         |                                                                      |
# Farxiga (SGLT2 inhibitor)

## Diabetes / cardiovascular risk reduction

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III Dapa-HF  
NCT03036124 | Patients With Chronic Heart Failure (CHF)       | 4,500    | • Arm 1: Farxiga 10mg or 5 mg QD + standard of care therapy  
• Arm 2: Placebo + standard of care therapy  
• Global trial - 20 countries | • Primary endpoint: Time to the first occurrence of any of the components of the composite: CV death or hospitalisation for heart failure (HF) or an urgent HF visit | • FPCD: Q1 2017  
• Data anticipated: 2019 |
| Phase III Dapa-CKD  
NCT03036150 | Patients With Chronic Kidney Disease (CKD)      | 4,000    | • Arm 1: Farxiga 10mg or 5 mg QD  
• Arm 2: Placebo  
Global trial - 20 countries | • Primary endpoint: Time to the first occurrence of any of the components of the composite: ≥50% sustained decline in eGFR or reaching end stage renal disease (ESRD) or CV death or renal death | • FPCD: Q1 2017  
• Data anticipated: 2020 |
## Qtern (saxagliptin/dapagliflozin) (DPP-4/SGLT2 inhibitor)

### Type-2 diabetes

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III</strong></td>
<td><strong>NCT02284893</strong></td>
<td>Type-2 diabetes</td>
<td>420 • Arm 1: saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR • Arm 2: sitagliptin 100mg + Met IR/XR (Global trial – six countries)</td>
<td>• Primary endpoint: Mean change from baseline in HbA1c at week 24 &lt;br&gt;Secondary endpoints: &lt;br&gt;• The proportion of subjects achieving a therapeutic glycaemic response at week 24 defined as HbA1c&lt;7% &lt;br&gt;• Mean change in total body weight at week 24</td>
<td>• FPCD: Q1 2015 &lt;br&gt;• LPCD: Q3 2015 &lt;br&gt;• Data readout: Q3 2016 &lt;br&gt;• Primary endpoint met</td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td><strong>NCT02419612</strong></td>
<td>Type-2 diabetes</td>
<td>440 • Arm 1: saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR • Arm 2: glimeperide 1-6mg + Met IR/XR (Global trial – 10 countries)</td>
<td>• Primary endpoint: Mean change from baseline in HbA1c at week 52 &lt;br&gt;Secondary endpoints: &lt;br&gt;• Mean change from baseline in total body weight at week 52 &lt;br&gt;• The proportion of subjects achieving a therapeutic glycaemic response at week 52 defined as HbA1c&lt;7.0%</td>
<td>• FPCD: Q3 2015 &lt;br&gt;• LPCD: Q3 2016 &lt;br&gt;• Data anticipated: Q4 2017</td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td><strong>NCT02551874</strong></td>
<td>Type-2 diabetes</td>
<td>598 • Arm 1: saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR with or without SU • Arm 2: insulin glargine + Met IR/XR with or without SU (Global trial – 12 countries)</td>
<td>• Primary endpoint: Mean change from baseline in HbA1c at week 24 &lt;br&gt;Secondary endpoints: &lt;br&gt;• Mean change in total body weight at week 24 &lt;br&gt;• The proportion of subjects with confirmed hypoglycaemia at week 24</td>
<td>• FPCD: Q4 2015 &lt;br&gt;• LPCD: Q4 2016 &lt;br&gt;• Data anticipated: Q4 2017</td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td><strong>NCT02681094</strong></td>
<td>Type-2 diabetes</td>
<td>900 • Arm 1: saxagliptin 5mg + dapagliflozin 5mg + Met IR/XR • Arm 2: dapagliflozin 5mg + placebo + Met IR/XR • Arm 3: saxagliptin 5mg + placebo + Met IR/XR (Global trial – six countries)</td>
<td>• Primary endpoint: Mean change from baseline in HbA1c at week 24 &lt;br&gt;Secondary endpoints: &lt;br&gt;• The proportion of subjects achieving a therapeutic glycaemic response at week 24 defined as HbA1c&lt;7% &lt;br&gt;• Mean change in fasting plasma glucose at 24 weeks</td>
<td>• FPCD: Q1 2016 &lt;br&gt;• LPCD: Q4 2016 &lt;br&gt;• Data anticipated: Q4 2017</td>
</tr>
</tbody>
</table>
## Bydureon (GLP-1 receptor agonist)

### Type-2 diabetes

<table>
<thead>
<tr>
<th>Trial Description</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase IV</strong>&lt;br&gt;EXSCEL&lt;br&gt;NCT01144338&lt;br&gt;Partnered</td>
<td>Type-2 diabetes</td>
<td>14,742</td>
<td>• Arm 1: Bydureon once weekly 2mg SC&lt;br&gt;• Arm 2: Placebo&lt;br&gt;On a background of SoC medication, different degree of CV risk&lt;br&gt;Global trial</td>
<td>• Primary endpoint: Time to first confirmed CV event in the primary composite CV endpoint (CV death, non-fatal MI, non-fatal stroke)</td>
<td>• FPD: Q2 2010&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Data readout: Q3 2017&lt;br&gt;• Primary safety endpoint met&lt;br&gt;• Primary efficacy endpoint not met</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;DURATION 7&lt;br&gt;NCT02229383</td>
<td>Type-2 diabetes</td>
<td>440</td>
<td>• Arm 1: Bydureon once weekly 2mg SC + titrated basal insulin&lt;br&gt;• Arm 2: Placebo + titrated basal insulin&lt;br&gt;Double-blind 1:1 randomisation. Background therapy with or without metformin&lt;br&gt;Global trial</td>
<td>• Primary endpoint: Change in HbA1c from baseline at 28 weeks</td>
<td>• FPCD: Q3 2014&lt;br&gt;• LPCD: Q3 2016&lt;br&gt;• Data readout: Q4 2016&lt;br&gt;• Primary endpoint met</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;DURATION 8&lt;br&gt;NCT02229396</td>
<td>Type-2 diabetes</td>
<td>660</td>
<td>• Arm 1: Bydureon once weekly 2mg SC&lt;br&gt;• Arm 2: Forxiga 10mg&lt;br&gt;• Arm 3: Bydureon once weekly 2mg SC + Forxiga 10mg&lt;br&gt;Double-blind 1:1:1 randomisation. Background therapy with metformin 1500mg/day up to 2 months prior to screening&lt;br&gt;Global trial</td>
<td>• Primary endpoint: Change in HbA1c from baseline at 28 weeks</td>
<td>• FPCD: Q3 2014&lt;br&gt;• LPCD: H2 2017&lt;br&gt;• Data readout: Q3 2016 – 28-week data&lt;br&gt;Q1 2017 – 52-week data&lt;br&gt;• Primary endpoint met&lt;br&gt;• Data anticipated: H1 2018 – 104-week data</td>
</tr>
</tbody>
</table>
# Epanova (omega-3 carboxylic acids)

## Hypertriglyceridaemia

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III STRENGTH (CVOT) NCT02104817 | Patients with hypertriglyceridaemia and high cardiovascular disease risk | 13,000 | • Arm 1: Epanova 4g QD + statin  
• Arm 2: Placebo (corn oil) + statin  
Global trial – 22 countries | Primary endpoint: Composite of MACE | • FPCD: Q4 2014  
• LPCD: Q2 2017  
• Data anticipated: 2019 |
| Phase III NCT02463071 | Japanese patients with hypertriglyceridaemia | 375 | • Epanova 2g and 4g vs Placebo (after meal) daily for 52 weeks  
Global trial – one country | Primary endpoints:  
• Safety in Japanese patients  
• % change in triglycerides | • FPCD: Q2 2015  
• LPCD: Q1 2016  
• Data readout: Q2 2017 |
| Phase III EVOLVE II NCT02009865 | Severe hypertriglyceridaemia | 162 | • Arm 1: Epanova 2g QD  
• Arm 2: Placebo (olive oil)  
Global trial – seven countries | Primary endpoint: Change in serum triglycerides over 12 weeks | • FPCD: Q4 2013  
• LPCD: Q2 2015  
• Data readout: Q4 2015  
• Primary endpoint met |
| Phase II EFFECT I NCT02354976 | Overweight patients with hypertriglyceridaemia | 75 | • Epanova 4g vs Placebo vs Fenofibrate 200mg daily for 12 weeks  
Global trial – one country | Primary endpoints:  
• Reduction in liver fat content (%) at the end of 12 weeks compared to placebo  
• Reduction in liver fat content (%) at the end of 12 weeks compared to fenofibrate | • FPCD: Q3 2015  
• LPCD: Q2 2016  
• Data readout: Q4 2016 |
| Phase II EFFECT II NCT02279407 | Type-2 diabetes  
Liver fat >5.5% | 80 | • Arm 1: Epanova 4g QD  
• Arm 2: Placebo (olive oil)  
• Arm 3: Epanova 4g + Farxiga 10mg QD  
• Arm 4: Farxiga 10mg  
Local trial – one country | Primary endpoints:  
• Reduction in liver fat content (%) at the end of 12 weeks | • FPCD: Q1 2015  
• LPCD: Q4 2015  
• Data readout: Q2 2016 |
| Phase I PRECISE NCT02370537 | Pancreatic Exocrine Insufficiency (PEI) in patients with type-2 diabetes | 66 | • Arm 1: Epanova 4g single dose  
• Arm 2: Omacor 4g single dose  
Global trial – six countries in Europe | Primary endpoint: PEI, PK of Epanova and Omacor following a single oral dose in patients with different degrees of PEI | • FPCD: Q1 2015  
• LPCD: Q4 2015  
• Data readout: Q2 2016 |

---

**Trial**

- **Phase III STRENGTH (CVOT) NCT02104817**
- **Phase III NCT02463071**
- **Phase III EVOLVE II NCT02009865**
- **Phase II EFFECT I NCT02354976**
- **Phase II EFFECT II NCT02279407**
- **Phase I PRECISE NCT02370537**

**Population**

- Patients with hypertriglyceridaemia and high cardiovascular disease risk
- Japanese patients with hypertriglyceridaemia
- Severe hypertriglyceridaemia
- Overweight patients with hypertriglyceridaemia
- Type-2 diabetes  
Liver fat >5.5%
- Pancreatic Exocrine Insufficiency (PEI) in patients with type-2 diabetes

**Patients**

- 13,000
- 375
- 162
- 75
- 80
- 66

**Design**

- Arm 1: Epanova 4g QD + statin  
Arm 2: Placebo (corn oil) + statin  
Global trial – 22 countries
- Epanova 2g and 4g vs Placebo (after meal) daily for 52 weeks  
Global trial – one country
- Epanova 2g QD  
Arm 2: Placebo (olive oil)  
Global trial – seven countries
- Epanova 4g vs Placebo vs Fenofibrate 200mg daily for 12 weeks  
Global trial – one country
- Arm 1: Epanova 4g QD  
Arm 2: Placebo (olive oil)  
Arm 3: Epanova 4g + Farxiga 10mg QD  
Arm 4: Farxiga 10mg  
Local trial – one country
- Arm 1: Epanova 4g single dose  
Arm 2: Omacor 4g single dose  
Global trial – six countries in Europe

**Endpoints**

- Primary endpoint: Composite of MACE
- Primary endpoints:  
Safety in Japanese patients  
% change in triglycerides
- Primary endpoint: Change in serum triglycerides over 12 weeks
- Primary endpoints:  
Reduction in liver fat content (%) at the end of 12 weeks compared to placebo  
Reduction in liver fat content (%) at the end of 12 weeks compared to fenofibrate
- Primary endpoints:  
Reduction in liver fat content (%) at the end of 12 weeks
- Primary endpoint: PEI, PK of Epanova and Omacor following a single oral dose in patients with different degrees of PEI

**Status**

- FPCD: Q4 2014  
LPCD: Q2 2017  
Data anticipated: 2019
- FPCD: Q2 2015  
LPCD: Q1 2016  
Data readout: Q2 2017
- FPCD: Q4 2013  
LPCD: Q2 2015  
Data readout: Q4 2015  
Primary endpoint met
- FPCD: Q3 2015  
LPCD: Q2 2016  
Data readout: Q4 2016
- FPCD: Q1 2015  
LPCD: Q4 2015  
Data readout: Q2 2016
- FPCD: Q1 2015  
LPCD: Q4 2015  
Data readout: Q2 2016
# Symbicort (ICS/LABA)

## Mild asthma

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III   | Patients in need of GINA step-2 treatment | 3,850    | • Arm 1: Symbicort Turbuhaler 160/4.5 μg 'as needed' + Placebo Pulmicort Turbuhaler 200μg bid  
• Arm 2: Pulmicort Turbuhaler 200 μg bid + terbutaline 0.4mg Turbuhaler 'as needed'  
• Arm 3: terbutaline Turbuhaler 0.4mg 'as needed' + placebo Pulmicort Turbuhaler 200μg bid  
Global trial – 19 countries | • Primary endpoint: Well-controlled asthma weeks (primary)  
Secondary endpoints:  
• Time to first severe asthma exacerbation  
• Time to first moderate or severe asthma exacerbation  
• Average change from baseline in pre-dose FEV1 | • FPCD: Q4 2014  
• LPCD: Q3 2016  
• Data readout: Q3 2017  
• Primary endpoint met |
| SYGMA1      |                                          |          |                                                                       |                                                                           |                                                                       |
| NCT02149199 |                                          |          |                                                                       |                                                                           |                                                                       |
| Phase III   | Patients in need of GINA step-2 treatment | 4,214    | • Arm 1: Symbicort Turbuhaler 160/4.5μg 'as needed' + Placebo Pulmicort Turbuhaler 200μg bid  
• Arm 2: Pulmicort Turbuhaler 200μg bid + terbutaline 0.4mg Turbuhaler 'as needed'  
Global trial – 25 countries | • Primary endpoint: Annual severe asthma exacerbation rate (primary)  
Secondary endpoints:  
• Time to first severe asthma exacerbation  
• Average change from baseline in pre-dose FEV1  
• Time to trial specific asthma related discontinuation | • FPCD: Q1 2015  
• LPCD: Q3 2016  
• Data readout: Q3 2017  
• Primary endpoint met |
| SYGMA2      |                                          |          |                                                                       |                                                                           |                                                                       |
| NCT02224157 |                                          |          |                                                                       |                                                                           |                                                                       |

ICS = Inhaled corticosteroids  
LABA = Long Acting Beta Agonist  
GINA = Global Initiative for Asthma guidelines
# Eklira/Tudorza (LAMA)

**Chronic obstructive pulmonary disease (COPD)**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IV | NCT02375724 | Patients with COPD | 224 | • Arm 1: Eklira/Tudorza 400μg  
• Arm 2: Placebo to aclidinium bromide 400μg  
Global trial – five countries | • Primary endpoint: Change from baseline in overall E-RS Total score (i.e. score over the whole eight weeks study period)  
Secondary endpoints:  
• Change from baseline in overall E-RS Cough and Sputum domain score  
• Change from baseline in the LCQ Total score at Week 8. Average change from baseline in pre-dose FEV1 | • FPCD: Q1 2015  
• LPCD: Q3 2015  
• Data readout: Q1 2016 |
| Phase IV | ASCENT | Patients with moderate to very severe COPD | 4,000 | • Arm 1: Eklira/Tudorza 400μg  
• Arm 2: Placebo to aclidinium bromide 400μg  
Global trial – two countries | Primary endpoints:  
• Time to first Major Adverse Cardiovascular Event (MACE). Up to 36 Months  
• Rate of moderate or severe COPD exacerbations per patient per year during the first year of treatment  
Secondary endpoints:  
• Rate of hospitalisations due to COPD exacerbation per patient per year during the first year of treatment  
• Time to first MACE or other serious cardiovascular events of interest. Up to 36 Months | • FPCD: Q3 2013  
• LPCD: Q3 2016 |
| Phase IV | NCT02153489 | Patients with stable moderate and severe COPD | 30 | • Arm 1: Eklira/Tudorza 400μg  
• Arm 2: Placebo to aclidinium bromide 400μg  
Local trial – one country | • Primary endpoint: Change from baseline in normalised forced expiratory volume in one second (FEV1). Week 3. FEV1 over the 24-hour period (AUC0-24) will be measured following morning administration  
Secondary endpoint: Adverse events. Week 5 | • FPCD: Q2 2014  
• LPCD: Q1 2015  
• Data readout: Q4 2015 |

LAMA = Long Acting Muscarinic Agonist
## Eklira/Tudorza (LAMA)

### Chronic Obstructive Pulmonary Disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I | Healthy Chinese Subjects    | 18                 | Open-label, 2-period ascending dose incomplete block, cross-over study  | • To investigate the pharmacokinetics (PK) of aclidinium bromide and its metabolites after single and multiple doses (twice-daily [BID]) of aclidinium bromide 200 μg, 400 μg and 800 μg  
  • To evaluate the safety, and tolerability of aclidinium bromide 200 μg, 400 μg and 800 μg after single and multiple dose administration (twice-daily [BID]) | FPCD: H1 2018  
  Data readout: H2 2018 |

### NCT03276052

- **Arm 1**: Aclidinium bromide 200 μg
- **Arm 2**: Aclidinium bromide 400 μg
- **Arm 3**: Aclidinium bromide 800 μg

Global Study – 1 Country
## Duaklir Genuair (LAMA/LABA)

### Chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IIb | ACHIEVE                          | Patients with moderate COPD | 120          | • Arm 1: Duaklir Genuair 400/12 µg  
• Arm 2: Placebo to aclidinium/formoterol FDC 400/12 µg  
Global trial – one country                                                                                                    | • Primary endpoint: Change from baseline in normalised FEV1 AUC over the 12h period immediately after morning trial drug administration, AUC0-12/12h at Day 7 on treatment  
Secondary endpoint:  
• Change from baseline in FEV1 AUC0-6/6h at day one and day seven on treatment  
• Change from baseline in morning pre-dose FEV1 at day seven on treatment                                                                 | FPCD: Q3 2016  
LPCD: Q3 2016  
Data readout: Q1 2017 |
| Phase III | AMPLIFY                          | Patients with stable COPD    | 1,500       | • Arm 1: Duaklir Genuair 400/12 µg  
• Arm 2: aclidinium bromide 400µg  
• Arm 3: formoterol fumarate 12µg  
• Arm 4: tiotropium 18µg  
Global trial – 13 countries                                                                                                 | Primary endpoints:  
• Change from baseline in 1-hour morning post-dose dose FEV1 of Duaklir Genuair 400/12 µg compared to AB 400µg at week 24  
• Change from baseline in morning predose (trough) FEV1 of Duaklir Genuair 400/12 µg compared to FF 12µg at week 24  
• Change from baseline in morning predose (trough) FEV1 at week 24 comparing AB 400µg versus TIO 18µg                                                                 | FPCD: Q3 2016  
LPCD: Q4 2016  
Data readout Q3 2017  
Primary endpoint met |
| Phase III | AVANT                            | Patients with stable COPD    | 1,060       | • Arm 1: Duaklir Genuair 400/12 µg  
• Arm 2: aclidinium bromide 400 µg  
• Arm 3: formoterol fumarate 12 µg  
• Arm 4: tiotropium 18 µg  
Global Study – five countries                                                                                                 | Primary endpoints:  
• Change from baseline in 1-hour morning post-dose dose FEV1 of Duaklir Genuair 400/12 µg compared to Acldinium bromide at Week 24  
• Change from baseline in morning pre-dose (trough) FEV1 of Duaklir Genuair 400/12 µg compared to Formoterol fumarate at Week 24  
• Change from baseline in trough FEV1 of Acldinium bromide 400 µg compared to placebo at Week 24                                                                 | FPCD: Q1 2017  
Data anticipated: 2019 |

LAMA = Long Acting Muscarinic Agonist  
LABA = Long Acting Beta Agonist
## Duaklir Genuair (LAMA/LABA)

### Chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase IIa NCT03276078</td>
<td>Chinese patients with stable moderate to severe COPD</td>
<td>20</td>
<td>Single and multiple twice daily doses of inhaled aclidinium bromide/formoterol fumarate 400/12 μg</td>
<td>To evaluate the pharmacokinetics (PK) of aclidinium bromide, its metabolites LAS34850 and LAS34823 and formoterol after administration of aclidinium bromide/formoterol 400/12 μg twice-daily (BID) for five days. To evaluate the safety and tolerability of aclidinium bromide/formoterol 400/12 μg twice-daily (BID) administered for 5 days.</td>
<td>FPCD: Q4 2017. Data anticipated: H2 2018</td>
</tr>
</tbody>
</table>

**LAMA =** Long Acting Muscarinic Agonist  
**LABA =** Long Acting Beta Agonist
# Bevespi Aerosphere (LAMA/LABA)

## Chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III PINNACLE 1  &lt;br&gt; NCT01854645</td>
<td>Moderate to very severe COPD</td>
<td>2,103</td>
<td>Treatment (24-week Treatment Period)  &lt;br&gt; • Arm 1: GFF MDI (Bevespi Aerosphere) 14.4/9.6μg BID  &lt;br&gt; • Arm 2: GP MDI (PT001) 14.4μg BID  &lt;br&gt; • Arm 3: FF MDI (PT005) 9.6μg BID  &lt;br&gt; • Arm 4: Open-label tiotropium bromide inhalation powder 18μg QD  &lt;br&gt; • Arm 5: Placebo MDI BID  &lt;br&gt; Multicentre, randomised, double-blind, parallel-group, chronic dosing, placebo- and active-controlled  &lt;br&gt; US, Australia, New Zealand</td>
<td>• Primary endpoint: Change from baseline in morning pre-dose trough FEV1  &lt;br&gt; • FPCD: Q2 2013  &lt;br&gt; • LPCD: Q3 2014  &lt;br&gt; • Data readout: Q1 2015</td>
<td>phase III</td>
</tr>
<tr>
<td>Phase III PINNACLE 2  &lt;br&gt; NCT01854658</td>
<td>Moderate to very severe COPD</td>
<td>1,615</td>
<td>Treatment (24-week Treatment Period)  &lt;br&gt; • Arm 1: GFF MDI (Bevespi Aerosphere) 14.4/9.6μg BID  &lt;br&gt; • Arm 2: GP MDI (PT001) 14.4μg BID  &lt;br&gt; • Arm 3: FF MDI (PT005) 9.6μg BID  &lt;br&gt; • Arm 4: Placebo MDI BID  &lt;br&gt; Multicentre, randomised, double-blind, parallel group, chronic dosing and placebo-controlled  &lt;br&gt; US</td>
<td>• Primary endpoint: Change from baseline in morning pre-dose trough FEV1  &lt;br&gt; • FPCD: Q3 2013  &lt;br&gt; • LPCD: Q3 2014  &lt;br&gt; • Data readout: Q1 2015</td>
<td>phase III</td>
</tr>
<tr>
<td>Phase III PINNACLE 3  &lt;br&gt; NCT01970878</td>
<td>Moderate to very severe COPD</td>
<td>893</td>
<td>Treatment (28-week Treatment Period)  &lt;br&gt; • Arm 1: GFF MDI (Bevespi Aerosphere) 14.4/9.6μg BID  &lt;br&gt; • Arm 2: GP MDI (PT001) 14.4μg BID  &lt;br&gt; • Arm 3: FF MDI (PT005) 9.6μg BID  &lt;br&gt; • Arm 4: Placebo MDI BID  &lt;br&gt; Multicentre, randomised, double-blind, parallel-group and active-controlled  &lt;br&gt; US, Australia, New Zealand</td>
<td>• Primary endpoint: Change from baseline in morning pre-dose trough FEV1  &lt;br&gt; • FPCD: Q4 2013  &lt;br&gt; • LPCD: Q2 2014  &lt;br&gt; • Data readout: Q1 2015</td>
<td>phase III</td>
</tr>
</tbody>
</table>

LAMA = Long Acting Muscarinic Agonist  
LABA = Long Acting Beta Agonist  
GFF = Glycopyrronium and formoterol
## Bevespi Aerosphere (LAMA/LABA)

### Chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design (G = glycopyrronium, F = formoterol fumarate)</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PINNACLE 4</td>
<td>Moderate to very severe COPD</td>
<td>1,614</td>
<td>Treatments (24-week Treatment Period) • GFF MDI (Bevespi Aerosphere) 14.4/9.6μg (N=514) • GP 14.4μg (N=440) • FF 9.6μg (N=440) • Placebo (N=220) • US/China: Trough FEV1 at week 24 of treatment • EU/Hybrid: Co-primary = Trough FEV1; over week 24 of treatment and TDI score over 24 weeks Randomised, Double-Blind, Chronic-Dosing, Placebo-Controlled, Parallel-Group and Multi-Centre US, UK, Germany, Costa Rica, Hungary, Poland, Russia, South Korea, Taiwan, China, Japan</td>
<td>• Primary endpoint: change from baseline in morning pre-dose trough FEV1 of treatment [Time Frame: At Week 24] Assessed at week 24 for US/China and over weeks 12-24 for Japan, and over 24 weeks for EU/South Korea/Taiwan • Secondary endpoint: TDI score (co-primary endpoint for EU and Hybrid) [Time Frame: Over 24 weeks]</td>
<td></td>
</tr>
<tr>
<td>NCT02343458</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase IIIb</td>
<td>Moderate to very severe COPD</td>
<td>1,000</td>
<td>Treatments (24-week Treatment Period) • GFF MDI (Bevespi Aerosphere) 14.4/9.6μg • Umeclidinium/Vilanterol DPI 62.5/25μg Randomised, Double-Blind, Double-Dummy, Multicentre, Parallel Group US, Canada, Bulgaria, France, Hungary, Russia, Ukraine</td>
<td>Co-primary endpoints: • Change from baseline in morning pre-dose trough FEV1 over 24 weeks • Peak change from baseline in FEV1 within 2 hours post-dosing over 24 weeks</td>
<td></td>
</tr>
<tr>
<td>AERISTO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03162055</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
- **LAMA** = Long Acting Muscarinic Agonist
- **LABA** = Long Acting Beta Agonist
- **GFF** = Glycopyrronium and formoterol

---

**Approved medicines**
- Oncology
  - Late-stage development
  - Early development - IMED
  - Early development - MedImmune

**Respiratory**
- CVMD
  - Early development

**Other**
# Daliresp/Daxas (oral PDE4 inhibitor)

## Chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase IV</td>
<td>COPD</td>
<td>2,354</td>
<td>52W, randomised, DB with Daliresp 500µg OD vs placebo, in COPD on top of ICS/LABA</td>
<td>Primary endpoint: Rate of moderate or severe COPD exacerbations per subject per year&lt;br&gt;FPCD: Q4 2011&lt;br&gt;LPCD: Q1 2016&lt;br&gt;Data readout: Q4 2016</td>
<td>RESPOND&lt;br&gt;NCT01443845</td>
</tr>
<tr>
<td>Phase IV</td>
<td>COPD</td>
<td>1,323</td>
<td>12W, randomised, DB to evaluate tolerability and PK of Daliresp 500µg OD with an up-titration regimen during the first 4Ws, including an open label down-titration evaluating tolerability and PK of 250µg Daliresp OD in subjects not tolerating 500µg OD</td>
<td>Primary endpoint: Percentage of participants prematurely discontinuing trial treatment for any reason during the main period&lt;br&gt;FPCD: Q2 2014&lt;br&gt;LPCD: Q3 2015&lt;br&gt;Data readout: Q4 2016</td>
<td>OPTIMIZE&lt;br&gt;NCT02165826</td>
</tr>
<tr>
<td>Phase IIIb</td>
<td>COPD</td>
<td>158</td>
<td>16W, randomised, placebo-controlled, DB, parallel-group trial to assess the anti-inflammatory effects of Daliresp in COPD</td>
<td>Primary endpoint: Number of inflammatory cells CD8+ in bronchial biopsy tissue specimen (sub-mucosa) measured at randomisation and at the end of the intervention period&lt;br&gt;FPCD: Q1 2012&lt;br&gt;LPCD: Q1 2016&lt;br&gt;Data readout: Q4 2016</td>
<td>ROBERT&lt;br&gt;NCT01509677</td>
</tr>
</tbody>
</table>

ICS = Inhaled corticosteroids  
LABA = Long Acting Beta Agonist
# Fasenra (benralizumab, IL-5R mAb)

## Severe, uncontrolled asthma

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III CALIMA NCT01914757 | Severe, uncontrolled asthma, despite background controller medication, medium dose (MD) & high dose (HD) ICS + LABA ± chronic OCS Age 12-75 years | 1,026 HD + ~200 MD | • Arm 1: 30mg Q8w SC  
• Arm 2: 30mg Q4w SC  
• Arm 3: Placebo SC | 56-week trial  
Global trial – 11 countries | • Primary endpoint: Annual asthma exacerbation rate  
• Secondary endpoints: Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM | • FPFD: Q4 2013  
• Data readout: Q2 2016  
• Primary endpoint met |
| Phase III SIROCCO NCT01928771 | Severe, uncontrolled asthma, despite background controller medication HD ICS + LABA ± chronic OCS Age 12-75 years | 1,134 | • Arm 1: 30mg Q8w SC  
• Arm 2: 30mg Q4w SC  
• Arm 3: Placebo SC | 48-week trial  
Global trial – 17 countries | • Primary endpoint: Annual asthma exacerbation rate  
• Secondary endpoints: Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM | • FPFD: Q4 2013  
• Data readout: Q2 2016  
• Primary endpoint met |
| Phase III ZONDA NCT02075255 | Severe, uncontrolled asthma on HD ICS plus long-acting β2 agonist and chronic oral corticosteroid therapy Age 18-75 years | 210 | • Arm 1: 30mg Q8w SC  
• Arm 2: 30mg Q4w SC  
• Arm 3: Placebo SC | 46-week trial  
Global trial – 12 countries | • Primary endpoint: Reduction of oral corticosteroid dose | • FPFD: Q3 2014  
• Data readout: Q3 2016  
• Primary endpoint met |
| Phase III MELTEMI NCT02808819 | A multi-centre, open-label, safety extension trial with benralizumab for asthmatic adults on ICS plus LABA2 Agonist Age 18-75 years | 770 | • Arm 1: 30mg Q4w SC  
• Arm 2: 30mg Q8w SC | | • Primary endpoint: Safety and tolerability | • FPFD: Q2 2016  
• Data anticipated: 2019 |
| Phase III ALIZE NCT02814643 | A multi-centre, randomised, double-blind, parallel group, placebo-controlled, Phase IIIb trial to evaluate the potential effect of benralizumab on the humoral immune response to the seasonal influenza vaccination in adolescent and young adult patients with severe asthma Ages 12-21 years | 100 | • Arm1 30mg Q4w SC with one dose of seasonal influenza virus vaccine Intramuscular (IM) at week eight  
• Arm1 Placebo Q4w SC with one dose of seasonal influenza virus vaccine IM at week | Primary endpoints:  
• Post-dose strain-specific haemagglutination-inhibition (HAI) antibody geometric mean fold rises (GMFRs)  
• Post-dose strain-specific serum HAI antibody geometric mean titers (GMTs)  
• Proportion of patients who experience a strain-specific post-dose antibody response with antibody response defined as a ≥4-fold rise in HAI antibody titer | • FPFD: Q3 2016  
• Data readout: Q3 2017  
• Primary endpoint met |
## Fasenra (benralizumab, IL-5R mAb)

**Severe, uncontrolled asthma**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III  | BISE Asthmatic with FEV₁ (50-90% predicted) on low to medium dose inhaled corticosteroid Age 18-75 years | 200      | • Arm 1: 30mg Q4W SC  
• Arm 3: Placebo SC  
12-week trial  
Global trial – six countries | • Primary endpoint: Pulmonary function (FEV₁) | • FPCD: Q1 2015  
• Data readout: Q1 2016  
• Primary endpoint met |
| NCT02322775 |                                                                            |          |                                                                        |                                                                           |                                                                                                                                    |
| Phase III  | BORA Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12-75 years | 2,550    | • Arm 1: 30mg Q4W SC  
• Arm 2: 30mg Q8W SC*  
• Placebo administered at select interim visits to maintain blind between treatment arms  
56-week (adults)  
108-week (adolescents)  
Global trial | • Primary endpoint: Safety and tolerability | • FPCD: Q4 2014  
• Data anticipated: H2 2018 |
| NCT02258542 |                                                                            |          |                                                                        |                                                                           |                                                                                                                                    |
| Phase III  | GREGALE Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 18-75 years | 120      | • Arm 1: 30mg Q4W SC  
28-week (adults)  
Global trial – two countries | • Primary endpoint: Functionality, reliability, and performance of a pre-filled syringe with benralizumab administered at home | • FPCD: Q2 2015  
• Data readout: Q2 2016  
• Primary endpoint met |
| NCT02417961 |                                                                            |          |                                                                        |                                                                           |                                                                                                                                    |
| Phase III  | ARIA A double-blind, randomised, parallel group, placebo-controlled multi-centre trial to evaluate the effect of benralizumab on allergen-induced inflammation in Mild, atopic asthmatic Age 18-65 years | 38       | • Arm 1: 30mg Q4W SC  
• Arm 2: Placebo SC | • Primary endpoint: Safety and tolerability | • FPCD Q4 2016  
• Data anticipated: 2019 |
| NCT02821416 |                                                                            |          |                                                                        |                                                                           |                                                                                                                                    |

ICS = Inhaled corticosteroids  
LABA = Long Acting Beta Agonist
**Fasenra (benralizumab, IL-5R mAb)**

Severe, uncontrolled asthma

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III SOLANA</strong>&lt;br&gt;NCT02869438</td>
<td>Severe asthma&lt;br&gt;Age 18-75 years</td>
<td>230</td>
<td>Arm 1: 30mg Q4W SC&lt;br&gt;Arm 2: Placebo SC&lt;br&gt;16-week trial&lt;br&gt;Global trial – six countries</td>
<td>Primary endpoint: Onset and maintenance of effect on lung function</td>
<td>FPCL: Q4 2016&lt;br&gt;Data anticipated: H2 2018</td>
</tr>
<tr>
<td><strong>Phase III GRECO</strong>&lt;br&gt;NCT02918071</td>
<td>Severe asthma&lt;br&gt;Age 18-75 years</td>
<td>120</td>
<td>Open label 30mg Q4w&lt;br&gt;28-week trial&lt;br&gt;Global trial - two countries</td>
<td>Primary endpoint: % of patients/caregivers who successfully self administer at home</td>
<td>FPCL: Q4 2016&lt;br&gt;Data readout: Q4 2017&lt;br&gt;Primary endpoint met</td>
</tr>
<tr>
<td><strong>Phase IIIb ANDHI</strong>&lt;br&gt;NCT03170271</td>
<td>A Multicenter, Randomised, Double-blind, Parallel Group, Placebo Controlled, Phase 3b Study to Evaluate the Safety and Efficacy of Benralizumab 30 mg sc in Patients With Severe Asthma Uncontrolled on Standard of Care Treatment. Age 18-75</td>
<td>800</td>
<td>Arm 1: 30mg Q8W SC&lt;br&gt;Arm 2: placebo SC</td>
<td>Primary Endpoint: rate of asthma exacerbations&lt;br&gt;Secondary Outcome Measures: Saint George Respiratory Questionnaire (SGRQ)</td>
<td>FPCL: Q3 2017&lt;br&gt;Data anticipated 2019</td>
</tr>
<tr>
<td><strong>Phase I AMES</strong>&lt;br&gt;NCT02968914</td>
<td>Healthy Volunteer&lt;br&gt;Age 18-55 years</td>
<td>162</td>
<td>Open label study to compare 30 mg benralizumab PK administered by APFS or AI device&lt;br&gt;8-week study&lt;br&gt;Global trial – two countries</td>
<td>Primary endpoint: PK Comparability</td>
<td>FPCL: Q1 2017&lt;br&gt;Data readout: Q3 2017</td>
</tr>
</tbody>
</table>

ICS = Inhaled corticosteroids
LABA = Long Acting Beta Agonist
# Fasenra (benralizumab, IL-5R mAb)

## Chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III TERRANOVA NCT02155660 | Moderate to very severe COPD with exacerbation history | 2,168    | • Arm 1: 10mg Q8W SC  
• Arm 2: 30mg Q4W SC  
• Arm 3: 100mg Q8W SC  
• Arm 4: Placebo SC  
48-week trial  
Global trial – 23 countries | • Primary endpoint: Rate of COPD exacerbation | • FPCD: Q3 2014  
• Data anticipated: H2 2018 |
| Phase III GALATHEA NCT02138918 | Moderate to very severe COPD with exacerbation history | 1,626    | • Arm 1: 30mg Q4W SC  
• Arm 2: 100mg Q8W SC  
• Arm 3: Placebo SC  
48-week trial  
Global trial – 17 countries | • Primary endpoint: Rate of COPD exacerbation | • FPCD: Q3 2014  
• Data anticipated: H2 2018 |
# Calquence (acalabrutinib)

## Rheumatoid arthritis

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoint(s)</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02387762</td>
<td></td>
<td></td>
<td>Arm B: methotrexate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Late-stage pipeline
# Moxetumomab pasudotox (CD22 mAb)

## Blood cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III PLAIT NCT01829711 | Adults with relapsed or refractory hairy cell leukaemia (HCL) | 77       | • Multicentre, single-arm, open-label Phase III trial  
• Moxetumomab pasudotox IV at the recommended dose | • Primary endpoint: Rate of durable CR: CR maintained for > 180 days  
• Efficacy: CR rate, ORR, Duration of CR and ORR, time to response (TTR), PFS  
• Safety and tolerability  
• PK and immunogenicity | • FPcwd: Q2 2013  
• Data readout: Q3 2017  
• Primary endpoint met |
| Phase I NCT00586924 | Adults with relapsed refractory HCL | 49       | • Open-label dose escalation Phase I trial  
• Moxetumomab pasudotox IV | • Maximum tolerated dose (MTD) and efficacy | • FPcwd: Q2 2007  
• LPCD: Q1 2014  
• Data readout: Q2 2015 |
## Selumetinib (MEK-inhibitor)

### Thyroid cancer and other cancers

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III** | **ASTRA**<br>NCT01843062            | 304      | • Arm 1: selumetinib 75mg BiD 5 weeks duration + radioactive iodine (RAI) 100mCi<sup>a</sup>  
  Global trial – eight countries  
  *<sup>a</sup> Single dose of 100mCi<sup>131</sup>I administered following 4 weeks of selumetinib (or placebo) | • Primary endpoint: Complete remission (CR) rate at 18 months post-radioactive iodine | • FPCD: Q3 2013  
• LPCD: Q1 2016  
• Data anticipated: H1 2018 |
| **Phase II**  | **Paediatric Neurofibromatosis (PN) type 1**<br>NCT01362803<br>Partnered | 50       | • Single Arm: selumetinib 25mg/m² BiD with 2 strata:  
  • Stratum 1: PN related morbidity present at enrolment  
  • Stratum 2: No PN related morbidity present at enrolment | • Complete partial and complete response rate measured by volumetric MRI;  
• Duration of response and functional outcomes/QoL | • FPCD: Q3 2015  
• LPCD: Q4 2016 |
| **Phase I**   | **Advanced solid tumours**<br>NCT02586987 | 90       | • Dose escalation trial: Starting dose selumetinib 50mg bd 1 week on/1 week off – Imfinzi 20mg/kg Q4 – after 7 days of selumetinib dosing  
• Note: No escalation in Imfinzi dose; selumetinib escalation with 25mg bd increment / dose cohort | • Safety and tolerability  
• PK of selumetinib and Imfinzi and preliminary anti-tumour activity | • FPCD: Q4 2015 |
## Savolitinib (MET)
### Papillary renal cell and other cancers

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III**  | MET-Driven, Papillary renal cell cancer | 180      | • Arm 1: savolitinib 600mg QD  
• Arm 2: sunitinib 50mg QD (4 weeks on / 2 weeks off) Global trial | • Primary endpoint: PFS  
• Secondary endpoints include ORR, DoR and OS | FPCD: Q4 2017  
Data anticipated: 2021 |
| **NCT03091192** | Partnered                         |          |                                                                        |                                                              |                                 |
| **Phase I**    | Advanced cancer (all comers)      | ~70      | • Dose escalation trial  
Conducted in China                                                        | • Safety and tolerability                                   | FPCD: Q2 2013  
Data anticipated: H2 2018 |
| **NCT01985555** | Partnered                         |          |                                                                        |                                                              |                                 |
| **Phase I**    | NSCLC                             | ~53      | • Dose escalation trial  
Conducted in China                                                        | • Safety and tolerability                                   | FPCD: Q2 2015  
Data anticipated: H2 2018 |
| **NCT02374645** | Partnered                         |          |                                                                        |                                                              |                                 |
| **Phase II**   | Lung Pulmonary Sarcomatoid Carcinoma (PSC) | 45       | • Single arm trial: savolitinib 600mg QD  
Conducted in China                                                          | • ORR                                                       | FPCD: Q1 2017  
Data anticipated: 2019 |
| **NCT02897479** | Partnered                         |          |                                                                        |                                                              |                                 |

**Approved medicines**
- **Oncology**
  - Early development - MedImmune
  - Late-stage development

**Early development - IMED**
- Respiratory
- Other

**Late-stage development**
- CVMD
# Cediranib (VEGF-inhibitor)

## Ovarian cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase IIb</td>
<td>CONCERTO: Platinum resistant recurrent (PRR) ovarian cancer - heavily pre-treated BRCAwt</td>
<td>100</td>
<td>Cediranib 30 mg + Lynparza 200 mg bd</td>
<td>ORR DoR, DCR, QoL, OS; Safety</td>
<td>FPCD: Q1 2017</td>
</tr>
</tbody>
</table>

**VEGF** - Vascular endothelial growth factor
## ZS-9 (Sodium zirconium cyclosilicate)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase II</strong></td>
<td>Hyperkalaemia and moderate chronic kidney disease (CKD)</td>
<td>90</td>
<td>• Arm 1: Escalating TID doses (0.3g, 3g and 10g) of ZS US • Arm 2: Placebo TID US</td>
<td>• Primary endpoint: Change in serum potassium levels from baseline</td>
<td>• FPCD: Q4 2011 • LPCD: Q2 2012 • Data readout: Q2 2012</td>
</tr>
<tr>
<td>NCT01493024</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td>Hyperkalaemia</td>
<td>754</td>
<td>• Arm 1: ZS-9 1.25g TID for 48 hrs followed by QD for 12 days • Arm 2: ZS-9 2.5g TID for 48 hrs followed by QD for 12 days • Arm 3: ZS-9 5g TID for 48 hrs followed by QD for 12 days • Arm 4: ZS-9 10g TID for 48 hrs followed by QD for 12 days • Arm 5: Placebo TID for 48 hrs followed by QD for 12 days</td>
<td>• Primary endpoint: Change in serum potassium levels from baseline</td>
<td>• FPCD: Q4 2012 • LPCD: Q4 2013 • Data readout: Q4 2013 • Primary endpoint met</td>
</tr>
<tr>
<td>NCT01737697</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td>Hyperkalaemia</td>
<td>258</td>
<td>Open-label ZS-9 10g TID for 48 hrs followed by: • Arm 1: ZS-9 5g QD for 28 days • Arm 2: ZS-9 10g QD for 28 days • Arm 3: ZS-9 15g QD for 28 days • Arm 4: Placebo QD for 28 days</td>
<td>• Primary endpoint: Maintenance of normokalaemia</td>
<td>• FPCD: Q1 2014 • LPCD: Q3 2015 • Data readout: Q4 2014 • Primary endpoint met</td>
</tr>
<tr>
<td>NCT02088073</td>
<td>Participation in trial NCT02088073 NCT02107092</td>
<td>123</td>
<td>• Arm 1: ZS-9 10g QD for 11 months. Option to uptitrate to 15g QD or downtitrate to 5g QD and 5g QOD</td>
<td>• Primary endpoint: Maintenance of normokalaemia</td>
<td>• FPCD: Q2 2014 • LPCD: Q3 2015 • Data readout: Q3 2015</td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td>Hyperkalaemia</td>
<td>751</td>
<td>• Arm 1: ZS-9 5g QD for 12 months. Option to uptitrate to 10 and 15g QD or downtitrate to 5g QD and 5g QOD</td>
<td>• Primary endpoint: Safety and tolerability</td>
<td>• FPCD: Q2 2014 • LPCD: Q4 2016 • Data readout: Q2 2017 • Primary endpoint met</td>
</tr>
<tr>
<td>NCT02163499</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td>Hyperkalaemia</td>
<td>255</td>
<td>Open-label ZS-9 10g TID for 48 hrs followed by: • Arm 1: ZS-9 5g QD for 28 days • Arm 2: ZS-9 10g QD for 28 days • Arm 3: Placebo QD for 28 days</td>
<td>• Primary endpoint: Maintenance of normokalaemia</td>
<td>• FPCD: Q1 2017</td>
</tr>
<tr>
<td>NCT02875834</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase II/III</strong></td>
<td>Hyperkalaemia</td>
<td>102</td>
<td>Arm 1: ZS-9 5g TID for 48 hours Arm 2: ZS-9 10g TID for 48 hours Arm 3: Placebo TID for 48 hours Japan</td>
<td>• Primary endpoint: Exponential rate of change in serum potassium</td>
<td>• FPCD: Q2 2017</td>
</tr>
<tr>
<td>NCT03127644</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td>Hyperkalaemia</td>
<td>150</td>
<td>Arm 1: Open-label ZS 10g TID for up to 72 hrs followed by ZS-9 5g QD for 12 months. Option to uptitrate to 10 and 15g QD or downtitrate to 5g QOD (or 2.5g QD) Japan</td>
<td>• Primary endpoint: Safety and tolerability as measured by adverse events reporting, vital signs, ECGs, physical examinations and safety laboratory measurements</td>
<td>• FPCD: Q3 2017</td>
</tr>
</tbody>
</table>
# ZS-9 (Sodium zirconium cyclosilicate)

## Hyperkalaemia

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I  
NCT03283267 | Healthy Subjects | 22 | Arm 1: Open-label ZS 5g QD for 4 days  
Arm 2: Open-label ZS 10g QD for 4 days  
China | • Primary endpoint: Mean change from baseline to ZS treatment period in urine potassium excretion | • FPCD: Q4 2017  
• LPCD: Q4 2017 |
| Phase IIIb  
NCT03303521 | Patients on haemodialysis with persistent pre-dialysis hyperkalaemia | 180 | Arm 1: ZS 5g QD for 8 weeks on non-dialysis days. Option to uptitrate to 10 and 15g QD.  
Arm 2: Placebo QD for 8 weeks on non-dialysis days  
Global trial – four countries | • Primary endpoint: Proportion of patients who maintain a pre-dialysis serum K between 4.0-5.0 mmol/L on 3 out of 4 dialysis treatments following the long interdialytic interval | • FPCD: Q4 2017 |
## Roxadustat (HIF-PHI)

### Anaemia

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III ANDES | Anaemia in CKD patients not receiving dialysis                          | 900      | • Arm 1: roxadustat  
• Arm 2: placebo  
Global trial | Primary endpoint: Haemoglobin response                                      | • FPDC: Q4 2012  
• Data anticipated: 2018  
Sponsored by FibroGen |
| Phase III ALPS |                                       | 597      | • Arm 1: roxadustat  
• Arm 2: Placebo  
Global trial | Primary endpoint: Haemoglobin response                                      | • FPDC: Q2 2013  
• Data anticipated: 2018  
Sponsored by Astellas |
| Phase III DOLOMITES |                                       | 570      | • Arm 1: roxadustat  
• Arm 2: darbepoetin alfa  
Global trial | Primary endpoint: Haemoglobin response                                      | • FPDC: Q1 2014  
• Data anticipated: 2018  
Sponsored by Astellas |
| Phase III OLYMPUS |                                       | 2,700    | • Arm 1: roxadustat  
• Arm 2: Placebo  
Global trial | Primary endpoint: MACE                                                      | • FPDC: Q3 2014  
• Data anticipated: 2018  
Sponsored by AstraZeneca |
| Phase III ROCKIES | Anaemia in CKD in patients receiving dialysis                      | 2,100    | • Arm 1: roxadustat  
• Arm 2: epoetin alfa  
Global trial | Primary endpoint: MACE                                                      | • FPDC: Q3 2014  
• Data anticipated: 2018  
Sponsored by AstraZeneca |
| Phase III SIERRAS |                                       | 820      | • Arm 1: roxadustat  
• Arm 2: epoetin alfa  
Global trial | Primary endpoint: Haemoglobin response                                      | • FPDC: Q4 2014  
• Data anticipated: 2018  
Sponsored by FibroGen |
| Phase III PYRENEES |                                       | 838      | • Arm 1: roxadustat  
• Arm 2: erythropoiesis stimulating agent  
• Arm 3: darbepoetin alfa  
Global trial | Primary endpoint: Haemoglobin response                                      | • FPDC: Q4 2014  
• Data anticipated: 2018  
Sponsored by Astellas |

HIF-PHI = Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor

717x350 Oncology
717x383 Late-stage development
646x371 Early development - IMED
646x371 Early development - MedImmune

48
### Roxadustat (HIF-PHI)

#### Anaemia

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III HIMALAYAS</strong>&lt;br&gt;NCT02052310&lt;br&gt;Partnered</td>
<td>Anaemia in newly initiated dialysis patients</td>
<td>750</td>
<td>• Arm 1: roxadustat&lt;br&gt;• Arm 2: epoetin alfa&lt;br&gt;Global trial</td>
<td>Primary endpoint: Haemoglobin response</td>
<td>• FPCD: Q4 2013&lt;br&gt;• Data anticipated: 2018&lt;br&gt;Sponsored by FibroGen</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;NCT02652819&lt;br&gt;Partnered</td>
<td>Anaemia in CKD patients not receiving dialysis</td>
<td>150</td>
<td>• Arm 1: roxadustat&lt;br&gt;• Arm 2: placebo&lt;br&gt;China trial</td>
<td>Primary endpoint: Haemoglobin response</td>
<td>• FPCD: Q4 2015&lt;br&gt;• LPCD: Q2 2016&lt;br&gt;• Data readout: Q2 2017&lt;br&gt;• Primary endpoint met&lt;br&gt;Sponsored by FibroGen</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;NCT02652806&lt;br&gt;Partnered</td>
<td>Anaemia in CKD patients receiving dialysis</td>
<td>300</td>
<td>• Arm 1: roxadustat&lt;br&gt;• Arm 2: epoetin alfa&lt;br&gt;China trial</td>
<td>Primary endpoint: Haemoglobin response</td>
<td>• FPCD: Q4 2015&lt;br&gt;• LPCD: Q2 2016&lt;br&gt;• Data readout: Q2 2017&lt;br&gt;• Primary endpoint met&lt;br&gt;Sponsored by FibroGen</td>
</tr>
</tbody>
</table>

HIF-PHI = Hypoxia-Inducible Factor Prolyl Hydroxylase Inhibitor
**Trial** | **Population** | **Patients** | **Design** | **Endpoints** | **Status**
--- | --- | --- | --- | --- | ---
**Phase III**

**NCT02536508 (ETHOS)**
Moderate to very severe COPD
500
Treatments (52-week Treatment Period)
- BGF MDI 320/14.4/9.6µg
- GFF MDI 14.4/9.6µg
- BFF MDI 320/9.6µg
Randomised, double-blind, chronic-dosing, multi-centre Country – US
Primary endpoints:
- Bone Mineral Density sub-study Endpoint. Change from baseline in BMD of the lumbar spine measured using DXA scans of L1-L4 at week 52
- Ocular Sub-study Safety Endpoint Change from baseline in LOCS III at week 52.
- FPCD: Q3 2015
- LPCD: Q3 2016

**NCT02465567 (KRONOS)**
Moderate to very severe COPD
8,000 (possible increase by 4,000 after blinded sample size re-assessment)
Treatments (1-year Treatment Period)
- BGF MDI 320/14.4/9.6µg BID
- BGF MDI 160/14.4/9.6µg BID
- BFF MDI 320/9.6µg BID
- GFF MDL 14.4/9.6µg BID
Randomised, double-blind, multi-centre and parallel-group Multi-country
Primary endpoint: Rate of moderate or severe COPD exacerbations
Secondary endpoint: Time to first moderate or severe COPD exacerbation
- FPCD: Q3 2015

**NCT03262012 (Phase III)**
Moderate to very severe COPD
324
Treatments (28-week Treatment Period)
- BGF MDI 320/14.4/9.6µg
- GFF MDI 14.4/9.6µg
- BFF MDI 320/9.6µg
- Symbicort Turbuhaler 400/12µg
Randomised, double-blind, parallel-group, chronic dosing, multicenter Country: Japan
Primary outcome measures:
- Long-term safety and tolerability (52 weeks): adverse events, 12-lead ECG, laboratory tests, vital signs
- FPCD Q3 2016
- LPCD Q4 2017
# Tezepelumab (TSLP mAb)

**Severe, uncontrolled asthma**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III</strong></td>
<td><strong>NAVIGATOR</strong></td>
<td>1,060</td>
<td>• Arm 1: tezepelumab SC</td>
<td>• Primary endpoint: Annual asthma exacerbation rate</td>
<td>• FPCD: Q1 2018</td>
</tr>
<tr>
<td>NCT03347279</td>
<td><strong>Partnered</strong></td>
<td></td>
<td>• Arm 2: Placebo SC</td>
<td>• Secondary endpoints: Change from baseline in pre-BD FEV1, asthma related QoL (AQLQ(S)+12), asthma control (ACQ-6)</td>
<td>• Data anticipated: 2020</td>
</tr>
<tr>
<td></td>
<td>Severe asthma</td>
<td></td>
<td>52 week trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age 12-80 years</td>
<td></td>
<td>Global trial – 18 countries</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TSLP = thymic stromal lymphopoietin
# Anifrolumab (type I IFN receptor mAb)

## Systemic lupus erythematosus (SLE) / Lupus nephritis (LN)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III**  
NCT02446912 | Moderate to severe SLE  
TULIP SLE 1 | 450 | • Arm 1: 300mg IV anifrolumab Q4W for 48 weeks  
• Arm 2: 150mg IV anifrolumab Q4W for 48 weeks  
• Arm 3: Placebo IV Q4W for 48 weeks | • Primary endpoint: Response in SLE responder index at week 52 | • FPCD: Q3 2015  
• Data anticipated: H2 2018 |
| **Phase III**  
NCT02446899 | Moderate to severe SLE  
TULIP SLE 2 | 360 | • Arm 1: 300mg IV anifrolumab Q4W for 48 weeks  
• Arm 2: Placebo IV Q4W for 48 weeks | • Primary endpoint: Response in SLE responder index at week 52 | • FPCD: Q3 2015  
• Data anticipated: H2 2018 |
| **Phase II**  
NCT01438489 | Moderate to severe SLE patients | 307 | • Arm 1: 300mg IV anifrolumab Q4W for 48 weeks  
• Arm 2: Placebo IV Q4W for 48 weeks | • Primary endpoint: Response in SLE responder index at 6 months | • FPCD: Q1 2012  
• LPCD: Q1 2015  
• Data readout: Q3 2014 |
| **Phase II**  
NCT01753193 | Moderate to severe SLE patients | 218 | • Arm 1: anifrolumab, IV Q4W for 104 weeks | • Primary endpoint: Open-label extension to evaluate long-term safety and tolerability | • FPCD: Q1 2013  
• Data anticipated: H2 2018 |
| **Phase II**  
NCT01559090 | Japanese SLE patients | 17 | Open-label, dose escalation trial:  
• Arm 1: 100mg IV Q4W for 48 weeks then 300mg IV Q4W for 104 weeks  
• Arm 2: 300mg IV Q4W for 48 weeks then 300mg IV Q4W for 104 weeks  
• Arm 3: 1000mg IV Q4W for 48 weeks then 1000mg IV Q4W for 104 weeks | • Safety, tolerability, PK/PD | • FPCD: Q1 2012  
• Data readout: Q1 2015 |
| **Phase I**  
NCT02601625 | Healthy subjects | 30 | • Arm 1: 300mg SC single dose  
• Arm 2: 300mg IV single dose  
• Arm 3: 600 mg SC single dose | • Safety, tolerability, PK/PD | • FPCD: Q4 2015  
• LPCD: H1 2016  
• Data readout: Q3 2016 |
| **Phase II**  
NCT02962960 | Moderate to severe SLE patients | 32 | • Arm 1: 150mg SC every other week  
• Arm 2: 300mg SC every other week  
• Arm 3: Placebo SC every other week | • PK/PD, Safety, tolerability, Primary analysis at week 12, Secondary analysis at week 52 | • FPCD: Q1 2017  
• Data anticipated: H1 2018 |
| **Phase II**  
NCT02547922 | Active Proliferative LN (TULIP-LN1) | 150 | • Arm 1: 900 mg IV Q4W for 12 weeks then 300mg IV anifrolumab Q4W for 36 weeks  
• Arm 2: 300 mg IV anifrolumab Q4W for 48 weeks  
• Arm 3: Placebo IV Q4W for 48 weeks | • Response in proteinuria at week 52 | • FPCD: Q4 2015  
• Data anticipated: 2019 |
### Lanabecestat (BACE inhibitor)

#### Alzheimer’s disease

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III AMARANTH**  
NCT02245737 | Early Alzheimer’s disease patients | 2,218 | • Arm 1: lanabecestat 20mg once daily  
• Arm 2: lanabecestat 50mg once daily  
• Arm 3: Placebo once daily  
24-month treatment duration  
Global trial – 14 countries | • Primary endpoint: Changes in cognitive (ADAS-Cog 13) scale  
Secondary endpoints:  
• Changes in other cognitive and functional (ADCS-ADL) scales  
• Changes in composite scales (CDR-SB)  
• Changes in biomarkers and imaging assays  
• Safety and tolerability | • FPCD: Q4 2014  
• LPCD: Q3 2017  
• Data anticipated: 2019 |
| **Phase III AMARANTH - EXTENSION**  
NCT02972658  
Partnered | Early Alzheimer’s disease patients | 1,400 | • lanabecestat 20mg or 50mg once daily  
12-month delayed start treatment extension  
Global trial – 14 countries | • Primary endpoint: Delayed start analysis | • FPCD: Q1 2017  
• Data anticipated: 2020 |
| **Phase III DAYBREAK-ALZ**  
NCT02783573 | Mild Alzheimer’s disease patients | 1,899 | • Arm 1: lanabecestat 20 mg once daily  
• Arm 2: lanabecestat 50 mg once daily  
• Arm 3: placebo once daily  
18-month treatment duration + 18-month delayed start extension  
Global trial – 18 countries | • Primary endpoint: Changes in cognitive (ADAS-Cog 13) scale  
Secondary endpoints:  
• Changes in cognitive and functional (ADCS-ADL) scales  
• Changes in composite scales (CDR-SB)  
• Changes in biomarkers and imaging assays  
• Safety and tolerability | • FPCD: Q3 2016  
• Data anticipated: 2019 |
Early development - IMED (AstraZeneca Research and Early Development)
AZD0156 (ATM)
Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Solid tumours</td>
<td>130</td>
<td>• Arm 1: AZD0156 + Lynparza</td>
<td>• Safety, tolerability, PK and efficacy</td>
<td>• FPCD: Q4 2015</td>
</tr>
<tr>
<td>NCT02588105</td>
<td></td>
<td></td>
<td>• Arm 2: AZD0156 + irinotecan</td>
<td></td>
<td>• Data anticipated: 2018</td>
</tr>
</tbody>
</table>

Trial conducted in North America, Europe and South Korea.
# AZD1775 (WEE-1)

## Ovarian cancer, triple-negative breast cancer, small cell lung cancer (SCLC)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase II</strong>&lt;br&gt;NCT02272790</td>
<td>Platinum-resistant (PR) ovarian cancer</td>
<td>97</td>
<td>• Arm B: paclitaxel + AZD1775&lt;br&gt;• Arm C: carboplatin + AZD1775&lt;br&gt;Global trial</td>
<td>• Primary endpoint: ORR&lt;br&gt;• Secondary endpoints: Duration of Response (DOR), PFS, OS, Disease Control Rate, safety and tolerability</td>
<td>FPCD: Q1 2015</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;NCT02482311</td>
<td>Advanced solid tumours</td>
<td>97</td>
<td>• Monotherapy Safety Run-in (part A, N=12); solid tumours Expansions into specific tumour types, inc. ovarian cancer (BRCAm PARP failures and BRCAwt with three or more prior lines of treatment), triple negative breast cancer (TNBC) and SCLC&lt;br&gt;Conducted in US, Canada</td>
<td>• Safety and tolerability&lt;br&gt;• Secondary endpoints: Overall response rate, DCR, DoR, PFS</td>
<td>FPCD: Q3 2015&lt;br&gt;LPCD: Q4 2016</td>
</tr>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;NCT02610075</td>
<td>Advanced solid tumours</td>
<td>78</td>
<td>• Monotherapy&lt;br&gt;Dose escalation trial to determine MTD&lt;br&gt;Conducted in US</td>
<td>• Safety and tolerability</td>
<td>FPCD: Q4 2015&lt;br&gt;LPCD: Q3 2017</td>
</tr>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;NCT02511795</td>
<td>Advanced solid tumours</td>
<td>102</td>
<td>• Dose escalation trial to determine MTD (AZD1775 + Lynparza) followed by expansions into specific tumour types, incl ovarian cancer, triple negative breast cancer (TNBC) and small cell lung cancer (SCLC)&lt;br&gt;Conducted in US, Canada</td>
<td>• Safety and tolerability&lt;br&gt;• Secondary endpoints: Overall response rate, Disease Control Rate, Duration of Response, PFS</td>
<td>FPCD: Q3 2015</td>
</tr>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;NCT02617277</td>
<td>Advanced solid tumours</td>
<td>55</td>
<td>• Dose escalation trial to determine MTD (AZD1775 + Imfinzi)&lt;br&gt;Conducted in US</td>
<td>• Safety and tolerability</td>
<td>FPCD: Q4 2015</td>
</tr>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;NCT02341456</td>
<td>Advanced solid tumours</td>
<td>19</td>
<td>• Dose escalation trial to determine MTD (AZD1775 + carboplatin + paclitaxel: AZD1775 + Carbo)&lt;br&gt;Conducted in Australia, Japan and Republic of Korea</td>
<td>• Safety and tolerability</td>
<td>FPCD: Q1 2015&lt;br&gt;LPCD: Q2 2016&lt;br&gt;Data readout Q1 2018</td>
</tr>
</tbody>
</table>
### AZD1775 (WEE-1)

**Ovarian cancer, triple-negative breast cancer, small cell lung cancer (SCLC)**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D6014C00005</td>
<td>Advanced solid tumours</td>
<td>24</td>
<td>Open-label, randomised, 2-period crossover design:</td>
<td>• Primary endpoints: Plasma AUC, AUC0-t and Cmax</td>
<td></td>
</tr>
<tr>
<td>NCT03315091</td>
<td></td>
<td></td>
<td>• Fasted (Treatment A): Single dose 300 mg AZD1775</td>
<td>• Secondary endpoints: Plasma tmax, kz , 1/2, CL/F and Vz/F</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Fed (Treatment B): Single dose 300 mg AZD1775</td>
<td>• Safety and tolerability</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Conducted in Europe</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D6014C00006</td>
<td>Advanced solid tumours</td>
<td>30</td>
<td>Part A: caffeine (200mg), omeprazole (20mg) and midazolam (1mL of</td>
<td>• Primary endpoints:</td>
<td></td>
</tr>
<tr>
<td>NCT0333824</td>
<td></td>
<td></td>
<td>2mg/mL syrup) followed 7-14 days later by AZD1775 225mg bid for</td>
<td>• Part A: Plasma AUC, AUC0-t and Cmax for cocktail</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.5 days plus caffeine (200mg), omeprazole (20mg) and</td>
<td>parent compounds (midazolam, omeprazole and</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>midazolam (1mL of 2mg/mL syrup) on day 3.</td>
<td>caffeine)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Part B: 7-14 days after end of Part A, AZD1775 225mg BID for 2.5</td>
<td>• Part B: dECG intervals (QTcF) for absolute values</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>days.</td>
<td>and time-matched change from baseline</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Conducted in US</td>
<td>• Secondary endpoints:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Plasma tmax, kz, CL/F and Vz/F for cocktail parent compounds (midazolam,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>omeprazole, and caffeine). Plasma AUC, AUC0-t, tmax, Cmax, kz,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>and kz for cocktail metabolites (1'-hydroxy-</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>midazolam, 5-hydroxy-omeprazole, and</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>paraxanthine) and the AUC and Cmax ratios in</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>relation to parent compound.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Plasma AZD1775 Day 1: Part B only: AUC0-12,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>tmax, and Cmax Plasma AZD1775 Day 3: Parts A &amp;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>B: AUC0-12, tmax, Cmax, Cmin, Cavg, CLass/F and</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FI; Part B only: RAUC0-12 and Rcmax</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• dECG intervals (heart rate, RR, PR, QRS, QTcB, QTcF and QT) for</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>absolute values and time-matched change from baseline; changes in</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>dECG morphology</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Safety and tolerability</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D6014C00007</td>
<td>Advanced solid tumours</td>
<td>54</td>
<td>AZD1775 monotherapy once daily.</td>
<td>• Safety and tolerability</td>
<td></td>
</tr>
<tr>
<td>NCT03313557</td>
<td></td>
<td></td>
<td>Conducted in US and Europe</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Approved medicines**

- **Oncology**
  - Late-stage development
  - Early development
- **Respiratory**
  - Early development - MedImmune
  - Other
## Vistusertib (AZD2014) (TORC 1/2)

### Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II     | 2L oestrogen-receptor positive (ER+) metastatic breast cancer                | 316      | • Arm 1: Faslodex  
• Arm 2: Faslodex + vistusertib 50mg BD continuous dosing  
• Arm 3: Faslodex + vistusertib 125mg BD two days on, 5 off  
• Arm 4: Faslodex + everolimus  
Multicentre: European sites | • Primary endpoint: PFS  
• Secondary endpoint: OS      | • FPCD: Q2 2014  
• LPCD: H2 2016  
• Data readout: Q4 2017 | **Phase II**
**MANTA**
NCT02216786
Partnered |
| Phase I      | Japanese Patients with Advanced Solid Malignancies                         | 18       | Open label  
Monotherapy and combination with paclitaxel cohorts                   | Safety and tolerability of AZD2014 monotherapy and in combination with paclitaxel  
PK                                          | • FPCD: Q2 2015  
• Data readout: Q4 2017 |
| Phase III/I  | Postmenopausal women with locally advanced/metastatic oestrogen receptor positive (ER+) breast cancer | 225      | Part A – Phase I triplet dose finding to determine the maximum tolerated dose (MTD) of the triplet (vistusertib + palbociclib + fulvestrant)  
Part B – Phase I single arm expansions (vistusertib + palbociclib + Faslodex)  
Part C – randomised, double-blind, placebo-controlled, stratified, parallel group extension at RP2D for triplet combination (vistusertib + palbociclib + Faslodex vs matching vistusertib placebo + palbociclib + Faslodex) | Primary endpoints:  
• Part A: Safety and tolerability of the triplet. MTD and recommended dose for Parts B and C  
• Part B: Safety and tolerability  
• Part C: PFS  
Secondary endpoints: Best Objective Response Rate (BOR) and Objective Response Rate (ORR) | • FPCD: Q1 2016  
• Data anticipated: 2019 |
| Phase III/I  | Relapsed/Refractory B-cell Malignancies                                    | 59       | Part 1: Identify a dose and schedule for vistusertib in combination with acalabrutinib  
Part 2: Evaluation of the safety of acalabrutinib and vistusertib when coadministered  
Number of participants experiencing dose-limiting toxicities  
Incidence of adverse events from the combination of acalabrutinib and vistusertib | Primary endpoints:  
• Safety and tolerability  
Secondary endpoints:  
• Overall response rate, Duration of response, Durable response rate, PFS  
PK                                          | • FPCD: Q3 2016  
• Data anticipated: 2019 |
| Phase III/I  | Relapsed/Refractory B-cell Malignancies                                    | 59       | Part 1: Identify dose and schedule for vistusertib + acalabrutinib  
Part 2: Single arm expansions to further explore tolerability, PK and clinical activity of vistusertib + acalabrutinib  
Conducted in US, EU                         | —                                                | • FPCD: Q3 2017  
• Data anticipated: 2019 |

**Phase I**
NCT02398747

**Phase III/I**
PASTOR
NCT02599714

**Phase I/II**
NCT03205046
Partnered

**Phase I/II**
NCT03205046
Partnered

---

**Approved medicines**

**Oncology**

- Late-stage development
  - IMED
- Early development - MedImmune

**CVMD**

- Respiratory
- Other
# AZD1390 (ATM BBB)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Subjects</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy Volunteers</td>
<td>8</td>
<td>• Positron-Emission Tomography (PET) Study</td>
<td>• Brain distribution of AZD1390 to assess if [11C]AZD1390 crosses the brain barrier in healthy volunteers</td>
<td>• FCPCD: Q4 2017</td>
</tr>
<tr>
<td>NCT03215381</td>
<td></td>
<td></td>
<td>• [11C]AZD1390 Microdose administered by IV bolus</td>
<td>• Data anticipated: 2018</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Trial conducted in a single centre in Sweden</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## AZD2811 (AURN)

### Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Solid tumours</td>
<td>72</td>
<td>• Arm 1: AZD2811 dose escalation • Arm 2: AZD2811 dose expansion</td>
<td>• Safety and tolerability</td>
<td>FPCD: Q4 2015</td>
</tr>
<tr>
<td>NCT02579226</td>
<td></td>
<td></td>
<td></td>
<td>• Pharmacokinetics and efficacy</td>
<td>Data anticipated: 2019</td>
</tr>
<tr>
<td>Phase I</td>
<td>Acute Myeloid Leukaemia/High-Risk Myelodysplastic Syndrome</td>
<td>36</td>
<td>• Part A: AZD2811 single agent dose escalation cohorts • Part B: AZD2811 dose expansion to further explore the tolerability, PK and clinical activity.</td>
<td>• Safety and tolerability</td>
<td>FPCD: Q3 2017</td>
</tr>
<tr>
<td>NCT03217838</td>
<td></td>
<td></td>
<td></td>
<td>• Pharmacokinetics and efficacy</td>
<td>Data anticipated: 2019</td>
</tr>
<tr>
<td>Phase I</td>
<td>Solid tumours</td>
<td>72</td>
<td>• Arm 1: AZD2811 dose escalation • Arm 2: AZD2811 dose expansion</td>
<td>• Safety and tolerability</td>
<td>FPCD: Q4 2015</td>
</tr>
<tr>
<td>NCT02579226</td>
<td></td>
<td></td>
<td></td>
<td>• Pharmacokinetics and efficacy</td>
<td>Data anticipated: 2019</td>
</tr>
<tr>
<td>Phase I</td>
<td>Acute Myeloid Leukaemia/High-Risk Myelodysplastic Syndrome</td>
<td>36</td>
<td>• Part A: AZD2811 single agent dose escalation cohorts • Part B: AZD2811 dose expansion to further explore the tolerability, PK and clinical activity.</td>
<td>• Safety and tolerability</td>
<td>FPCD: Q3 2017</td>
</tr>
<tr>
<td>NCT03217838</td>
<td></td>
<td></td>
<td></td>
<td>• Pharmacokinetics and efficacy</td>
<td>Data anticipated: 2019</td>
</tr>
</tbody>
</table>
## AZD4547 (FGFR)
### Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase II</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| GLOW | Female ER+ breast cancer patients whose disease has progressed following treatment with one prior endocrine therapy | 40 | • Part A: AZD4547 in ascending multiple doses in combination with 25mg exemestane  
• Part B:  
  • Arm 1: AZD4547 (dose from part A) + Faslodex  
  • Arm 2: placebo + Faslodex  
  Patients with FGFR1 polysomy (30 patients) or FGFR1 amplification (60 patients)  
Conducted in eight countries in Europe | • Part A: MTD of AZD4547 in combination with 25mg exemestane in three schedules of AZD4547  
• Part B Interim analysis: Tumour size analysis on 30 FGFR amplified patients  
• Part B Final analysis: PFS | • FPCD: Q4 2010  
• LPCD: Q1 2014  
• Data readout: Q3 2014 |
| SHINE | Advanced gastro-oesophageal cancer | 71 | • Arm 1 (FGFR2 polysomy): AZD4547 vs pacitaxel randomised 1:1 (30 to 80 patients)  
• Arm 2 (FGFR 2 low gene amplification: AZD4547 vs pacitaxel randomised 3:2 (25 to 80 patients)  
• Arm 3 (FGFR2 high gene amplification: AZD4547 vs pacitaxel randomised 3:2 (25 to 80 patients)  
Conducted in 16 countries across Europe and Asia | • Primary endpoint: PFS  
• Secondary endpoint: OS/Tumour size | • FPCD: Q4 2011  
• LPCD: Q2 2013  
• Data readout: Q1 2015 |
| **Phase I** | | | | | |
| | Advanced cancer who have failed standard therapy or for whom no standard therapy exists | 33 | • Part A: AZD4547 in ascending multiple doses given bd and od (c. 30 patients)  
• Part B: AZD4547 in patients whose tumours have FGFR amplification (c. eight patients)  
Conducted in Japan | • Part A: MTD and Recommended dose for Parts B and C  
• Part B: Safety and tolerability and preliminary anti-tumour activity | • FPCD: Q4 2010  
• LPCD: Q4 2012  
• Data readout: Q2 2013 |
| | Advanced cancer who have failed standard therapy or for whom no standard therapy exists | 94 | • Part A: Ascending oral doses of AZD4547 to define maximum tolerated dose (MTD) and/or continuous, tolerable recommended dose (RD)  
• Part B: Dose expansion phase at RD defined in Part A  
• Part C: Expansion phase in patients with FGFR1 and FGFR2 amplified tumours at the RD defined from Part A  
Conducted in seven countries across North America and Europe | • Part A: MTD and recommended dose for Parts B and C  
• Part B and C: Safety and tolerability, PK and preliminary anti-tumour activity | • FPCD: Q4 2009  
• LPCD: Q4 2013  
• Data readout: Q1 2015 |
| BISCAY | 2L muscle-invasive metastatic bladder cancer in patients who have failed prior therapy | 110 | • Multi-drug biomarker-directed trial  
• Arm 1: AZD4547  
• Arm 2: AZD4547 + Imfinzi  
• Arm 3: Lyrparpa + Imfinzi  
• Arm 4: AZD1775 + Imfinzi  
• Arm 5: Imfinzi  
• Arm 6: vistusertib + Imfinzi  
• Arm 7: AZD9150 + Imfinzi  
Planned in North America and Europe | • Safety and tolerability of the combinations  
• PK and preliminary anti-tumour activity | • FPCD: Q4 2016  
• Data anticipated: 2019 |
# AZD4573 (CDK9)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Relapsed/refractory haematologic malignancies</td>
<td>42</td>
<td>Dose Escalation in relapsed/refractory haematological malignancies AZD4573 will be administered 2 parallel arms of (1-6 cohorts of dose escalations) based on the haematological malignancy</td>
<td>• Primary-Safety/PK; secondary-efficacy trial</td>
<td>• FPCD: Q4 2017 • Data anticipated: 2019</td>
</tr>
<tr>
<td>NCT03263637</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* clinicaltrials.gov being updated
# AZD4635 (A<sub>2A</sub>R)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I| Phase Ia: patients with advanced solid tumours                              | 36 (estimated) | • Phase Ia: dose escalation to determine the Maximum Tolerated Dose (MTD) of AZD4635 given as monotherapy and in combination with Imfinzi. When the combination MTD is determined, additional patients with advanced solid malignancies will be enrolled to a dose expansion cohort to explore further the safety, tolerability, pharmacokinetics (PK), and biological activity  
  • Phase Ib will consist of an additional expansion phase in NSCLC at the combination MTD or maximum feasible dose  
  Both parts conducted at sites in the US | Primary Outcome Measure: Safety and tolerability  
  Secondary Outcome Measures:  
  • PK of AZD4635 as monotherapy and combination with Imfinzi  
  • Preliminary assessment of anti-tumour activity | • FP:Q2 2016  
• Data anticipated: 2018 |
| NCT02740985 | Phase Ib: patients with advanced NSCLC who have previously received anti-PD-1 therapy, but either failed to respond or stopped responding after an initial response | 15 |  |  |  |
AZD4785 (KRAS antisense oligonucleotide)

Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>NCT03101839</td>
<td>Phase Ia: patients with advanced solid tumours which harbour mutations of KRAS.</td>
<td>30 (estimated)</td>
<td>• Phase Ia: dose escalation to determine the Maximum Tolerated Dose (MTD) of AZD4785 given as monotherapy. When the MTD is determined, additional patients with advanced solid malignancies may be enrolled to explore further the safety, tolerability, pharmacokinetics (PK), and biological activity</td>
<td>Primary Outcome Measure: Safety and tolerability</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Phase Ib: patients with advanced NSCLC with tumours harbouring mutations of KRAS.</td>
<td>20</td>
<td>• Phase Ib will consist of an expansion phase in patients with KRASm NSCLC at the MTD or maximum feasible dose. To be conducted at sites in the USA and UK</td>
<td>Secondary Outcome Measures:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Pharmacokinetics of AZD4785</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Change in KRAS mRNA from baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Objective clinical response</td>
</tr>
</tbody>
</table>

Primary Outcome Measure: Safety and tolerability
Secondary Outcome Measures:
- Pharmacokinetics of AZD4785
- Change in KRAS mRNA from baseline
- Objective clinical response

FPCD: Q2 2017
Data anticipated: 2019
## AZD5069 (CXCR2)

### Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase Ib/II | Squamous Cell Carcinoma of the Head & Neck (HNSCC) | 405 | Dose Escalation advanced solid and blood cancers  
- Arm A1: AZD9150/Imfinzi  
- Arm A2: AZD5069/Imfinzi  
- Arm A4: AZD9150/Imfinzi/Ifreone  
- Arm A5: AZD5069/Imfinzi/Ifreone  
Dose Expansion 2L HNSCC:  
- Arm B1: AZD9150  
- Arm B2: AZD5069  
- Arm B3: AZD9150/Imfinzi  
- Arm B4: AZD5069/Imfinzi  
- Arm B5: AZD9150 Mono  
- Arm B6: AZD5069 Mono  
- Arm B7: AZD9150/Imfinzi (1L HNSCC) | • Safety/Efficacy trial | • FPCD: Q3 2015  
• Data anticipated: 2019 |
| Phase Ib/II | Metastatic Pancreatic Ductal Carcinoma | 16 | Dose escalation and expansion Arms:  
Imfinzi in combination with nab-paclitaxel and gemcitabine  
Imfinzi in combination with AZD5069 | • Safety/Efficacy trial | • FPCD: Q1 2016  
• Data anticipated: 2018 |

*clinicaltrials.gov being updated*
## AZD5153 (BRD4)

### Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I/Ib</td>
<td>Relapsed/refractory solid tumours, lymphomas</td>
<td>54</td>
<td>Dose Escalation advanced solid and lymphomas 6 dose escalation cohorts of AZD5153 Dose and schedule from dose escalation will be applied in dose expansion Phase in platinum-resistant or platinum-refractory high grade serous (HGS) ovarian cancer</td>
<td>• Primary-Safety/secondary-Efficacy trial</td>
<td>• FPCD: Q2 2017 • Data anticipated: 2019</td>
</tr>
</tbody>
</table>

NCT03205176

* clinicaltrials.gov being updated
# AZD5363 (AKT) Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Breast and gynaecological cancers with PIK pathway mutation</td>
<td>12-24 per arm (Parts E &amp; F)</td>
<td>AZD5363 400mg BD 4 days on 3 days off combined with 500mg fulvestrant (initially 12 patients per arm with option to expand to 24 patients in one or more arms) • Part E arm 1: ER+ Breast with AKT-1 mutation (prior Faslodex resistance) • Part E arm 2: ER+ Breast with AKT-1 mutation (first exposure to Faslodex) • Part F arm 1: ER+ Breast with PTEN mutation (prior Faslodex resistance) • Part F arm 2: ER+ Breast with PTEN mutation (first exposure to Faslodex)</td>
<td>• Safety and tolerability • ORR • Clinical Benefit Rate at 24 weeks (CBR24) [Parts E &amp; F only]</td>
<td>• Data anticipated: 2019</td>
</tr>
<tr>
<td>NCT01226316</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune

Oncology
Respiratory
Other

IMED
CVMD
# AZD5991 (MCL1)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Relapsed/refractory haematologic malignancies</td>
<td>30</td>
<td>Dose Escalation in relapsed/refractory haematological malignancies</td>
<td>• Primary-Safety/secondary-Efficacy trial</td>
<td>• FPCD: Q3 2017</td>
</tr>
<tr>
<td>NCT03218683</td>
<td></td>
<td></td>
<td>5 dose escalation cohorts of AZD5991</td>
<td>• Data anticipated: 2019</td>
<td></td>
</tr>
</tbody>
</table>

* clinicaltrials.gov being updated
# AZD6738 (ATR)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Solid tumours</td>
<td>160</td>
<td>• Arm 1: AZD6738 + carboplatin</td>
<td>• Safety and tolerability</td>
<td>FPCD: Q4 2014</td>
</tr>
<tr>
<td>NCT02264678</td>
<td></td>
<td></td>
<td>• Arm 2: AZD6738 dose escalation, AZD6738 + Lynparza</td>
<td>• PK and efficacy</td>
<td>Data anticipated: Q1 2018</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 3: AZD6738 + Imfinzi</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trial conducted in North America, Europe and South Korea</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Trial conducted in North America, Europe and South Korea.
## AZD8186 (PI3Kb/d)

### Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase I**<br>NCT01884285 | Advanced Castrate Resistant Prostate Cancer /sqNSCLC /TNBC and patients with known PTEN-deficient/ mutated or PIK3CM mutated/ amplified advanced solid malignancies | 153 | • Part A: AZD8186 monotherapy in ascending intermittent doses in 3 schedules  
• Part B: AZD8186 monotherapy at recommended dose and schedule(s) from Part A in PTEN deficient patients with advanced cancer  
• Part C: Combination AZD8186 added to abiraterone acetate (with prednisone) in PTEN deficient metastatic castrate resistant prostate cancer (mCRPC) patients. Initial dose/ schedule confirmation phase using AZD8186 monotherapy recommended dose/ schedule from Part A and the labelled dose of abiraterone followed by an expansion cohort to explore clinical activity  
• Part D: Combination AZD8186 and AZD2014 (a novel dual mTORC ½ inhibitor). Initial dose/ schedule determination phase in same patient population as Part A followed by an expansion cohort in PTEN deficient TNBC patients to explore clinical activity | • Part A: PK, MTD and Recommended dose and schedule(s) for Part B  
• Part B: Safety, tolerability and preliminary assessment of anti-tumour activity (POM)  
• Part C: PK, safety, tolerability and recommended dose/ schedule of AZD8186 in combination with abiraterone. Preliminary assessment of anti-tumour activity of AZD8186 in combination with abiraterone  
• Data anticipated: 2019 |
# AZD9150 (STAT3)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase Ib/II</td>
<td>Squamous Cell Carcinoma of the Head &amp; Neck (HNSCC)</td>
<td>405</td>
<td>Dose Escalation advanced solid and blood cancers</td>
<td>• Safety/Efficacy trial</td>
<td>• FPCD: Q3 2015</td>
</tr>
<tr>
<td>NCT02499328</td>
<td></td>
<td></td>
<td>• Arm A1: AZD9150/Imfinzi</td>
<td></td>
<td>• Data anticipated: 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm A2: AZD5069/Imfinzi</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm A4: AZD9150/Imfinzi/Xtreme</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm A5: AZD5069/Imfinzi/Xtreme</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dose Expansion 2L HNSCC:</td>
<td></td>
<td>• Arm B1: AZD9150</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm B2: AZD5069</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm B3: AZD9150/Imfinzi</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm B4: AZD5069/Imfinzi</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm B5: AZD9150 Mono</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm B6: AZD5069 Mono</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm B7: AZD9150/Imfinzi (1L HNSCC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase Ib/II</td>
<td>Diffuse Large B-cell Lymphoma</td>
<td>190</td>
<td>Dose escalation and expansion Arms:</td>
<td>• Safety/Efficacy trial</td>
<td>• FPCD: Q3 2016</td>
</tr>
<tr>
<td>NCT02549651</td>
<td></td>
<td></td>
<td>• Experimental Arm: Imfinzi monotherapy</td>
<td></td>
<td>• Data anticipated: 2021</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Experimental Arm: Imfinzi and Tremelimunab</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Experimental Arm: Imfinzi and AZD9150</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* clinicaltrials.gov being updated
# AZD9496 (SERD)

## Breast cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I        | ER+ Breast Cancer   | ~50      | • This is an open label randomised multicentre pre-surgical pharmacodynamics study to compare and assess the biological effects of AZD9496 and Faslodex in postmenopausal women with oestrogen receptor positive (ER+) human epidermal growth factor receptor 2 negative (HER2-) primary breast cancer. Patients will receive AZD9496 or Faslodex and will have a pre-dose and an on-treatment core biopsy after 5-14 days of commencing treatment. | • Primary Outcome Measures: Pharmacodynamics changes to estrogen receptor (ER) expression following treatment with AZD9496 or Faslodex  
• Secondary Outcome Measures: Pharmacodynamics changes to Ki67 and progesterone receptor (PgR) expression following treatment with AZD9496 or Faslodex | FPCD: Q4 2017  
LPCD: Q4 2018  
Data readout: Q2 2019 |
| Phase I        | ER+ Breast Cancer   | ~50      | • This is a Phase I open label multicentre trial of AZD9496 administered orally in patients with advanced ER+ HER2 negative breast cancer. The trial design allows an escalation of dose with intensive safety monitoring to ensure the safety of patients. The trial will determine the maximum tolerated dose. In addition, expansion cohort(s) at potential therapeutic dose(s) in patients with or without ESR1 mutations will be enrolled to further determine the safety, tolerability, pharmacokinetics and biological activity of AZD9496 | • Primary Outcome Measures: Safety and tolerability  
• Secondary Outcome Measures: Single and multiple dose pharmacokinetics of AZD9496 4β-hydroxycholesterol concentration in blood  
• Anti-tumour activity | FPCD: Q4 2014  
LPCD: Q2 2016  
Data readout: Q2 2017 |
| Phase I        | Healthy subjects    | 14       | • This is a Phase I open label single centre trial to assess the pharmacokinetics and safety of different forms and formulations of AZD9496 in healthy subjects | • Primary Outcome Measures: Pharmacokinetics for AZD9496 and its metabolites  
• Secondary Outcome Measures: Safety and tolerability | FPCD: Q2 2016  
LPCD: Q3 2018  
Data readout: Q2 2017 |
## AZD4831 & AZD5718
### Cardiovascular disease

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZD4831 (MPO) Phase I NCT02712372</td>
<td>Healthy subjects</td>
<td>~96</td>
<td>SAD trial (one trial site in Germany) • Planned to investigate 6 different dose levels vs placebo but up to 10 cohort may be used</td>
<td>Safety and tolerability • PK parameters</td>
<td>FPCD: Q3 2016 • LPCD: Q4 2016 • Data readout Q2 2017</td>
</tr>
<tr>
<td>AZD4831 (MPO) Phase I NCT03136991</td>
<td>Healthy subjects</td>
<td>~40</td>
<td>MAD (one trial site in USA) • The planned number of cohorts is four but up to five cohorts may be included</td>
<td>Safety and tolerability • PK parameters</td>
<td>FPCD: Q2 2017</td>
</tr>
<tr>
<td>AZD5718 (FLAP) Phase I NCT02632526</td>
<td>Healthy subjects</td>
<td>96</td>
<td>SMAD trial (one trial site in UK) SAD • Oral administration MAD • The planned number of cohorts is four but up to six cohorts may be included • Once or twice daily oral administration of AZD5718</td>
<td>Safety and tolerability • PK parameters, bioavailability</td>
<td>FPCD: Q1 2016 • LPCD: Q3 2016 • Data readout: Q4 2016</td>
</tr>
<tr>
<td>AZD5718 (FLAP) Phase I NCT02963116</td>
<td>Healthy subjects</td>
<td>12</td>
<td>DDI/BA study (one trial site in UK) A Randomised, 5-Period, 5-Treatment, Single-Dose, open-label, cross-over study to • estimate the effect of AZD5718 on the Pk of Crestor • Assess the relative bioavailability of AZD5718 oral suspension vs AZD5718 IR tablet formulation • Assess the food effect of AZD5718</td>
<td>PK and bioavailability • To further assess the safety of single doses of AZD5718 in healthy subjects</td>
<td>FPCD: Q2 2016 • LPCD: Q1 2017 • Data readout Q2 2017</td>
</tr>
<tr>
<td>AZD5718 (FLAP) Phase 2A NCT03317002</td>
<td>Coronary Artery Disease (CAD)</td>
<td>100</td>
<td>Phase 2A trial • Arm 1: AZD5718 Dose A • Arm 2: AZD 5718 Dose B • Arm 3: Placebo Global trial – three countries in Europe</td>
<td>Primary endpoint: PD effect of AZD5718 by assessment of u-LTE4</td>
<td>FPCD: Q4 2017</td>
</tr>
</tbody>
</table>
# AZD8601 (VEGF-A)

## Cardiovascular disease

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Type 2 diabetic patients</td>
<td>~60</td>
<td>SAD trial (one trial site in Germany)</td>
<td>• Safety and tolerability</td>
<td>FPCD: Q1 2017</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Planned to investigate 3 different dose levels vs placebo but up to 5 cohort may be used</td>
<td></td>
<td>LPCD: Q3 2017</td>
</tr>
<tr>
<td>NCT02935712</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Verinurad (RDEA3170, URAT1 inhibitor)

Chronic kidney disease

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II| CKD patients with hyperuricaemia, albuminuria, and Type 2 diabetes         | 60       | • Arm A: verinurad 9 mg and febuxostat 80 mg  
• Arm B: Placebo  
The trial is a multi-centre trial conducted in the US | To assess the effects of intensive uric acid lowering therapy with RDEA3170 and febuxostat on UACR (urine albumin creatinine ratio) | FPCD: Q2 2017        |

| NCT03118739 |                                                                           |          |                                                                        |                                                                          |                     |

The trial is a multi-centre trial conducted in the US.
# Abediterol (AZD0548, LABA)

## Asthma

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Patients With Asthma on Inhaled Corticosteroids</td>
<td>12</td>
<td>A randomised, single-blind, placebo-controlled study to assess PK and safety of Abediterol 5 μg DPI given QD for 9 days, compared to placebo, in patients with asthma on ICSs</td>
<td>• To assess Cmax after single inhaled dose of Abediterol 5 μg. Cmax will be taken directly from the individual concentration-time curve&lt;br&gt;• To assess tmax after single inhaled dose of Abediterol 5 μg. tmax will be taken directly from the individual concentration-time curve</td>
<td>FPCD: Q3 2017&lt;br&gt;LPCD: Q4 2017&lt;br&gt;Data readout: H1 2018</td>
</tr>
</tbody>
</table>
## AZD1419 (TLR9 agonist)

### Asthma

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IIa INCONTRO NCT02898662 | Adults with eosinophilic, moderate to severe asthma on ICS + LABA background treatment | 81       | • Arm 1: AZD1419, once-weekly adaptive dosing (4mg, 1mg, 8mg)  
• Arm 2: placebo  
Inhaled (nebulised) administration  
Trial conducted in EU | • Time to loss of asthma control                                             | • FPCD: Q4 2016  
• LPCD: Q4 2017  
• Data anticipated: H2 2018                                       |

ICS = Inhaled corticosteroids  
LABA = Long Acting Beta Agonist
# AZD5634 (epithelial NaC inhibitor)

## Cystic fibrosis

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>Part A: 57 Part B: 6</td>
<td>SAD. A Phase I, Randomised, Single-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability and Pharmacokinetics of AZD5634 Following Single-Ascending Inhaled Doses (Part A) and After Single Inhaled and Intravenous Doses (Part B) in Healthy Subjects</td>
<td>Primary Endpoint • Safety and tolerability Secondary Endpoint • PK parameters</td>
<td>• FPCD: Q1 2016 • LPCD: Q3 2016 • Data readout: Q2 2017</td>
</tr>
<tr>
<td>Phase Ib</td>
<td>Patients with Cystic Fibrosis</td>
<td>12</td>
<td>PoM. A Phase Ib, Randomised, Blinded, Placebo-Controlled Cross-Over Study to Assess the Effect of AZD5634 on Mucociliary Clearance as Well as Safety, Tolerability and Pharmacokinetic Parameters Following Single Inhaled Dose Administration to Patients with Cystic Fibrosis</td>
<td>Primary Endpoint • Mucociliary clearance (MCC) Secondary Endpoint • PK parameters • Safety and tolerability</td>
<td>• FPCD: Q2 2017</td>
</tr>
</tbody>
</table>

**Approved medicines**

- Oncology
  - Late-stage development
  - Early development - IMED
- Respiratory
  - Early development - MedImmune

---

78
AZD7594 (inhaled SGRM)

Asthma/chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II NCT02479412  | Patients with mild to moderate asthma | 48       | A randomised, double blind, multiple dosing (14 days), placebo-controlled, incomplete block cross-over, multi-centre trial to assess efficacy and safety of three dose levels of AZD7594, given once daily by inhalation, in patients with mild to moderate asthma | Primary: morning trough forced expiratory volume in one second (FEV1)     | • FPCD: Q3 2015  
• LPCD: Q4 2015  
• Data readout: Q3 2016                                                    |
| Phase I NCT02967159   | Healthy subjects                  | 32       | A randomised open label cross-over study to evaluate pharmacokinetics and safety of single inhaled doses of abediterol and AZD7594 given alone, in fixed dose combination (FDC) and in free combination using dry powder inhaler (DPI), in male healthy volunteers | PK, safety and tolerability                                               | • FPCD: Q4 2016  
• LPCD: Q1 2017  
• Data readout: Q2 2017                                                    |
| Phase I NCT02928354   | Healthy subjects                  | 12       | This study is an open label, randomised, three-way cross-over study to assess the effect of particle size on the PK and safety of single inhaled doses of AZD7594 in healthy subjects (males aged 18 to 55 years [inclusive]) The study will be performed at a single study centre | PK and safety                                                             | • FPCD: Q4 2016  
• LPCD: Q1 2017  
• Data readout: Q2 2017                                                    |
| Phase I NCT01636024   | Healthy subjects                  | 73       | SAD/MAD  
A Phase I, single centre, double-blind, randomised, placebo controlled, parallel-group trial to assess the safety, tolerability, Pharmacokinetics and Pharmacodynamics after single and multiple ascending inhaled doses of AZD7594 in healthy male Subjects – suspension inhaled via Spira nebuliser  
Trial conducted in the UK                                                  | Safety and tolerability                                                  | • FPCD: Q4 2012  
• LPCD: Q2 2013  
• Data readout: Q4 2013                                                    |
| Phase I NCT02648438   | Healthy subjects                  | 30       | An open label, partially randomised, four-period trial in healthy male subjects to investigate the bioavailability and pharmacokinetics of a single dose of AZD7594 when administered intravenousally, orally and inhaled via two different dry powder inhalers (DPI) and a pressurised metered-dose inhaler (pMDI) | Bioavailability and pharmacokinetics                                    | • FPCD: Q1 2016  
• LPCD: Q2 2016  
• Data readout: Q3 2016                                                    |
| Phase I NCT02645253   | Healthy subjects                  | 27       | A phase I, randomised, single-blind, placebo-controlled, sequential-group, single-centre trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses of AZD7594 given once daily as inhaled formulation in healthy Japanese men | Safety and tolerability                                                  | • FPCD: Q1 2016  
• LPCD: Q2 2016  
• Data readout: Q4 2016                                                    |
## AZD7594 (inhaled SGRM)

### Asthma/chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>18</td>
<td>A randomised open label three-way cross-over study in healthy male volunteers to investigate the effect of particle size on PK following a single inhaled dose of AZD7594 via a dry powder inhaler (DPI)</td>
<td>• PK</td>
<td>• FPCD: Q4 2016</td>
</tr>
<tr>
<td>NCT02928354</td>
<td></td>
<td></td>
<td></td>
<td>• Safety and tolerability</td>
<td>• LPCD: Q1 2017</td>
</tr>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>32</td>
<td>A randomised open label cross-over study to evaluate the pharmacokinetics and safety of single inhaled doses of abediterol and AZD7594 given alone, in fixed dose combination and in free combination, using DPI, in male healthy volunteers</td>
<td>• PK</td>
<td>• FPCD: Q4 2016</td>
</tr>
<tr>
<td>NCT02967159</td>
<td></td>
<td></td>
<td></td>
<td>• Safety and tolerability</td>
<td>• LPCD: Q1 2017</td>
</tr>
</tbody>
</table>
AZD8871 (MABA2)

Chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IIa  
NCT02971293 | Moderate to severe COPD | 42       | Comprises 3 treatment periods of 14 days each separated by a washout period of 28 to 35 days  
• AZD8871 600 μg once daily (double-blind)  
• AZD8871 100 μg once daily (double-blind)  
• Placebo (double-blind)  
Global study – 2 countries (UK & Germany) | Primary Endpoint:  
• To evaluate the efficacy of inhaled AZD8871 in patients with moderate to severe COPD  
Secondary Endpoint:  
• To investigate the PK of AZD8871 and its metabolites after multiple dose administration of AZD8871 in patients with moderate to severe COPD | • FPCD: Q1 2017  
• LPCD: Q1 2017  
• Data readout: Q3 2017 |

| Phase I  
NCT03159442 | Healthy Japanese Volunteers | 24       | MAD study with 3 dose levels - 300 μg, 600 μg, and 900 μg (plus placebo control group in each dose level).  
Global Study – 1 country (UK) | Primary Endpoint:  
• The primary objective is to investigate the safety and tolerability of AZD8871 at steady state  
Secondary Endpoint:  
• To characterize the PK of AZD8871 and its metabolites LAS191861 and LAS34850 after multiple doses of AZD8871 and assess the time required to reach steady state, the degree of accumulation and the time dependency | • FPCD: Q3 2017  
• LPCD: Q3 2017  
• Data readout: Q4 2017 |
<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I   | Healthy subjects    | 71       | MAD trial with a total of 6 dose levels of AZD9567: 10 mg, 20 mg, 40 mg, 80 mg and 125 mg as well as with 3 dose levels of prednisolone: 5 mg, 20 mg and 40 mg | Primary Endpoint:  
  • To assess the safety and tolerability of AZD9567 following multiple oral ascending doses in subjects with BMI between 28 and 38 kg/m² and with a positive glucose tolerance test (7.8 to 11.0 mmol/L)  
  Secondary Endpoints:  
  • To characterise the pharmacokinetics of AZD9567 following multiple oral administration of ascending doses  
  • To characterise the pharmacodynamics of AZD9567 assessed as effect on glucose homeostasis through OGTT (oral glucose tolerance test) in comparison with prednisolone | FPCD: Q2 2016  
  Data anticipated: H1 2018 |
| Phase IIa | Patients with active RA | 40   | A Phase II, Randomised, Double-blind, Parallel Study to Assess the Efficacy, Safety and Tolerability of AZD9567 compared to Prednisolone 20 mg in patients with active Rheumatoid Arthritis | Primary Endpoint:  
  To assess the efficacy of AZD9567, 40 mg, compared to prednisolone 20 mg in patients with active rheumatoid arthritis in spite of stable treatment with conventional and/or s.c./i.v. biological DMARDs  
  Secondary Endpoints:  
  • To further assess the efficacy of AZD9567, 40 mg, compared to prednisolone 20 mg in patients with active rheumatoid arthritis in spite of stable treatment with conventional and/or s.c./i.v. biological DMARDs  
  (e.g. SJC 66/TJC68, ACR response criteria)  
  • To evaluate the pharmacokinetic profile of AZD9567 | FPCD: Q1 2018 |
## AZD0284 (RORγ)

### Plaque psoriasis vulgaris

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>80</td>
<td>Part 1 (SAD) • Seven different dose levels investigated vs placebo</td>
<td>• Safety and tolerability and PK following oral administration</td>
<td>FPCD: Q3 2016</td>
</tr>
<tr>
<td>NCT02976831</td>
<td></td>
<td></td>
<td>• oral administration</td>
<td>• Preliminary assessment of the effect of food on the single dose PK parameters of AZD0284</td>
<td>LPCD: Q2 2017</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Part 2 (MAD) • Three different dose levels investigated vs placebo in healthy subjects</td>
<td>• Safety and tolerability &amp; PK in healthy subjects following administration of multiple ascending oral doses</td>
<td>FPCD: Q1 2017</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• oral administration</td>
<td>• Proof of Mechanism (PoM) confirmed by demonstrating that oral dosing of AZD0284 reduces IL-17 secretion by ex vivo stimulated whole blood T cells</td>
<td>LPCD: Q1 2017</td>
</tr>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>6</td>
<td>A Phase I, single centre, open-label, non-randomised, single dose study performed in 6 healthy male subjects aged 18 to 65 years, inclusive. The study will assess the absolute bioavailability of a single oral dose of AZD0284 and the pharmacokinetics (PK) of a single intravenous (IV) microdose of [14C]AZD0284 in healthy male and female subjects. Oral AZD0284 and [14C]AZD0284 intravenous solution are referred to as the investigational products in this study</td>
<td>• Determination of absolute bioavailability of AZD0284</td>
<td>FPCD: Q1 2017</td>
</tr>
<tr>
<td>NCT03029741</td>
<td></td>
<td></td>
<td></td>
<td>• Safety and tolerability of AZD0284</td>
<td>LPCD: Q1 2017</td>
</tr>
</tbody>
</table>
Early development - MedImmune Research & Early Development
# Imfinzi (PD-L1 mAb)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Compound</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III Study 1108</td>
<td><strong>Imfinzi</strong></td>
<td>Solid tumours</td>
<td>1,022</td>
<td>• Dose Escalation: 5 cohorts at Q2W and 1 cohort at Q3W</td>
<td>• Safety</td>
<td>FPCD: Q3 2012</td>
</tr>
<tr>
<td>NCT01693562</td>
<td></td>
<td></td>
<td></td>
<td>• Dose Expansion: 18 tumour type cohorts at the Q2W MTD defined during dose escalation; one cohort at 20mg Q4W Global trial – eight countries</td>
<td>• Optimal biologic dose</td>
<td>LPCD: Q4 2015 Data readout: Ongoing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Secondary endpoints include PK, immunogenicity and anti-tumour activity</td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td><strong>Imfinzi</strong></td>
<td>Myelodysplastic syndrome</td>
<td>73</td>
<td>Dose-escalation and dose-expansion trial</td>
<td>• Safety and tolerability of monotherapy and combination</td>
<td>FPCD: Q2 2014 Data anticipated: 2020</td>
</tr>
<tr>
<td>NCT02117219</td>
<td>and azacitidine (Vidaza)</td>
<td></td>
<td></td>
<td>• Part 1: <strong>Imfinzi</strong></td>
<td>• Secondary endpoints include duration of response, PFS and OS, PK and immunogenicity</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Part 2 Arm 1: <strong>Imfinzi and tremelimumab</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Part 2 Arm 2: <strong>Imfinzi, tremelimumab, and azacitidine</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Global trial – four countries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 1</td>
<td><strong>Imfinzi</strong></td>
<td>Solid tumours</td>
<td>42</td>
<td>Multi-centre, open-label, single-arm trial for adult subjects</td>
<td>• Safety, PK, number of subjects reporting infusion related reaction</td>
<td>FPCD: Q3 2016 Data anticipated: 2018</td>
</tr>
<tr>
<td>NCT02900157</td>
<td></td>
<td></td>
<td></td>
<td>US and Japan trial centers</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Approved medicines

- **Oncology**
- **Late-stage development**
- **Early development - IMED**
- **Early development - MedImmune**

### CVMD

- **Respiratory**
- **Other**
# Imfinzi (PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase Ib/II STUDY 21 NCT02340975 | Gastric or GEJ adenocarcinoma | 236 | • Arm A: Imfinzi + tremelimumab 2L  
• Arm B: Imfinzi 2L  
• Arm C: tremelimumab 2L  
• Arm D: Imfinzi + tremelimumab 3L US and ROW trial centres | • Primary endpoints: Safety & tolerability, ORR, PFS  
• Secondary endpoints: DCR, OS, DoR, PD-L1 Expression | • FPCD: Q2 2015  
• Data anticipated: H2 2018 |
| Phase Ib/II STUDY 22 NCT02519348 | Hepatocellular Carcinoma | 144 | • Arm A: Imfinzi + tremelimumab  
• Arm B: Imfinzi 2L  
• Arm C: tremelimumab 2L | Primary endpoints: Safety and tolerability, ORR, PFS  
Secondary endpoints: DCR, OS, DoR, PD-L1 Expression | • FPCD: Q4 2015  
• Data anticipated: H2 2018 |
| Phase Ib STUDY 006 NCT02000947 | NSCLC (Immunoxt naive and Immunoxt pretreated patient cohorts) | 459 | • Dose Escalation: minimum 5 cohorts exploring various treme Q4W and Imfinzi IV Q4W dose combinations, higher dose levels and alternate Q2 schedule added with amendment  
• Dose Expansion: MTD for the combination in escalation to be explored in expansion North American trial centres, exploration of ex-US countries for expansion into EU and ROW | Primary endpoints: Safety  
Optimal biologic dose for the combination  
Secondary endpoints include Antitumour activity, PK and immunogenicity | • FPCD: Q4 2013  
• LPCD: H1 2017  
• Data anticipated: H2 2018 |
| Phase I STUDY 10 NCT02261220 | Solid tumours (Basket trial) | 380 | • Dose Exploration: 2 cohorts exploring various Q4W treme and Imfinzi dose combinations and 2 cohorts exploring various Q2W treme and Imfinzi dose combinations  
• Dose Expansion: MTD for the combination in escalation to be explored in expansion cohorts specific for each of 7 tumour types North American trial centres | Primary endpoints: Safety  
Optimal biologic dose for the combination  
Secondary endpoints include anti-tumour activity, PK/PD and immunogenicity | • FPCD: Q4 2014  
• LPCD: H1 2017  
• Data anticipated: H1 2018 |
| Phase I STUDY 11 NCT02262741 | HNSCC | 71 | • Arm A: treatment-naive, PD-L1+, combo  
• Arm B: treatment-naive, PD-L1-, combo  
• Arm C: PD-1/PD-L1 refractory, combo North American trial centres | Primary endpoint: Safety & tolerability  
Secondary endpoints: OR, DC, DoR, PFS, OS, PKPD, immunogenicity and biomarkers | • FPCD: Q4 2014  
• LPCD: Q3 2016  
• Data readout: Q4 2017 |
| Phase Ib STUDY 23 NCT02549651 | Diffuse Large B cell Lymphoma | 207 | • Arm A: Imfinzi  
• Arm B: Imfinzi + tremelimumab  
• Arm C: tremelimumab + AZD9150 US and European trial centres | Primary endpoint: Safety & tolerability  
Secondary endpoints: OR, DC, DoR, PFS, OS, PKPD, immunogenicity and biomarkers | • FPCD: Q3 2016  
• Data anticipated: 2022 |
**Imfinzi (PD-L1 mAb)**

+ **Iressa** (gefitinib)

Non-small cell lung cancer (NSCLC)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>NSCLC (Escalation phase)</td>
<td>56</td>
<td>Escalation phase&lt;br&gt;Standard 3+3 design with 28 days DLT period&lt;br&gt;- Iressa (QD) + Imfinzi IV</td>
<td>Primary endpoints:&lt;br&gt;- Safety&lt;br&gt;- Optimal biologic dose for the combination&lt;br&gt;- Secondary endpoints: tumour response (CR, PR, SD, PD), Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics</td>
<td>FPCD: Q2 2014&lt;br&gt;LPCD: Q2 2015&lt;br&gt;Data anticipated: 2019</td>
</tr>
<tr>
<td>NCT02088112</td>
<td>EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase)</td>
<td></td>
<td>Expansion phase&lt;br&gt;- Iressa (QD) + Imfinzi IV recommended dose&lt;br&gt;Global trial – three countries</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Approved medicines**

**Oncology**

Late-stage development

Early development - IMED

Early development - MedImmune

**CVMD**

**Respiratory**

**Other**
# Imfinzi (PD-L1 mAb) + MEDI0680 (PD-1 mAb)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I | Advanced malignancies (escalation phase) | 96 | Dose-escalation phase  
  • Imfinzi IV + MEDI0680 IV  
  Dose-expansion phase at selected dose from dose-escalation phase  
  • Imfinzi IV + MEDI0680 IV recommended dose | Primary endpoints:  
  • Safety  
  • Determination of MTD  
  Secondary endpoints include tumour response such as objective response rate, disease control rate, progression-free survival, duration of response, OS, immunogenicity, pharmacokinetics, pharmacodynamics | FPCD: Q2 2014  
  Data anticipated: 2021 |
| Phase I | Advanced malignancies (escalation phase) | 58 | Dose-escalation phase  
  • MEDI0680 IV | Primary endpoint: Safety & Tolerability  
  Secondary endpoints include tumour response such as objective response rate, immunogenicity, pharmacokinetics, pharmacodynamics | FPCD: Q4 2013  
  Data anticipated: Q2 2017 |
**Imfinzi (PD-L1 mAb) + dabrafenib (BRAF inhibitor) / trametinib (MEK inhibitor)**

**Melanoma**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I/II</td>
<td>Metastatic or unresectable melanoma</td>
<td>68</td>
<td>Dose Escalation:</td>
<td>Primary endpoints:</td>
<td>FPCD: Q1 2014</td>
</tr>
<tr>
<td>NCT02027961</td>
<td>BRAF mutation+ (Cohort A)</td>
<td></td>
<td>• Cohort A dabrafenib 150mg BiD/ trametinib 2mg QD/ Imfinzi IV</td>
<td>• Safety</td>
<td>LPCD: Q2 2015</td>
</tr>
<tr>
<td></td>
<td>BRAF wild type (Cohorts B&amp;C)</td>
<td></td>
<td>• Cohort B trametinib 2mg QD/ Imfinzi IV</td>
<td>• Optimal biologic dose for the combination</td>
<td>Data anticipated: H1 2018</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Cohort C trametinib 2mg QD/ Imfinzi IV</td>
<td>• Secondary endpoints include objective response and disease control, duration of response, progression-free survival and OS, pharmacokinetics and immunogenicity</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose Expansion:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Each cohort will be expanded at the MTD to enroll a total of 20</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>subjects per cohort</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Global trial – two countries</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Imfinzi (PD-L1 mAb) + monalizumab (NKG2a mAb)**

### Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Advanced solid tumours</td>
<td>175</td>
<td>Escalation phase</td>
<td>Primary endpoints:</td>
<td>FPCD: Q2 2016</td>
</tr>
<tr>
<td>NCT02671435</td>
<td></td>
<td></td>
<td>• monalizumab + Imfinzi IV</td>
<td>• Safety</td>
<td>Data anticipated: 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Expansion phase</td>
<td>• Optimal biologic dose for the combination</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• monalizumab + Imfinzi IV recommended dose</td>
<td>• Secondary endpoints include tumour response (CR, PR, SD, PD), Objective</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Global Trial</td>
<td>response rate, disease control rate, progression-free survival,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>immunogenicity, pharmacokinetics, pharmacodynamics</td>
<td></td>
</tr>
</tbody>
</table>
# MEDI0457 + *Imfinzi* (PD-L1 mAb)

**Squamous cell carcinoma of the Head and Neck (SCCHN)**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase Ib/IIa</td>
<td>Human papillomavirus (HPV) Associated Recurrent/Metastatic Head and Neck Cancer</td>
<td>50</td>
<td>Multi-centre, open label study to evaluate the safety and efficacy of combination treatment with MEDI0457 and <em>Imfinzi</em></td>
<td>Primary endpoints: Safety &amp; Tolerability, ORR Secondary endpoints: PK, ADA, DCR, OS, PFS</td>
<td>FPCD: 3Q 2017 Data Anticipated: 2019</td>
</tr>
<tr>
<td>NCT03162224</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MEDI0562 (OX40 mAb)
MEDI0562 (OX40 mAb) + *Imfinzi* (PD-L1 mAb) or tremelimumumab (CTLA-4 mAb)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase I**<br>NCT02318394 | Advanced malignancies | 106 | Dose-escalation phase  
• MEDI0562 IV  
Dose-expansion phase  
• MEDI0562 IV recommended dose | Primary endpoints:  
• Safety  
• Determination of MTD  
Secondary endpoint: preliminary anti-tumour activity, pharmacokinetics, biomarker activity, and immunogenicity | • FPCD: Q1 2015  
• Data anticipated: 2020 |
| **Phase I**<br>NCT02705482 | Advanced malignancies | 404 | Arm A: MEDI0562 IV + *Imfinzi* IV  
Arm B: MEDI0562 IV + tremelimumab IV | Primary endpoint: Safety  
Secondary endpoint: preliminary anti-tumour activity, pharmacokinetics, and immunogenicity and pharmacodynamics | • FPCD: Q2 2016  
• Data anticipated: 2023 |
# MEDI1873 (GITR agonist)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Adult subjects with select advanced solid tumours</td>
<td>51</td>
<td>Dose-escalation phase • MEDI1873 IV US trial centres</td>
<td>Primary endpoints: • Safety • Determination of MTD • Secondary endpoints: preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity</td>
<td>FPCD: Q4 2015 • Data anticipated: 2021</td>
</tr>
<tr>
<td>NCT02583165</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Approved medicines**

- **Oncology**
  - Late-stage development
  - Early development - IMED
  - Early development - MedImmune

- **Respiratory**
- **CVMD**
- **Other**
# MEDI4276 (HER2 ADC mAb)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Advanced HER2+ metastatic breast and gastric cancer</td>
<td>Dose escalation Up to 66 Dose expansion Up to 150</td>
<td>• First-time-in-human Phase 1, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects</td>
<td>• Primary endpoint: safety • Secondary endpoints: anti-tumour activity, overall response, disease control, PFS, OS and change from baseline tumour size</td>
<td>FPCD: Q4 2015 Data anticipated: 2019</td>
</tr>
<tr>
<td>NCT02576548</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Approved medicines
- Oncology
  - Late-stage development
  - Early development - IMED
  - Early development - MedImmune

Early development - CVMD

Other
MEDI5083 + *Imfinzi* (PD-L1 mAb)

**Cancer**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I | Advanced Solid Tumours | 204      | Dose-escalation phase  
• Part 1: MEDI5083  
• Part 2: MEDI5083 + *Imfinzi* IV  
Dose expansion phase  
• Part 3: MEDI5083 recommended dose + *Imfinzi* IV  
US and Australian trial centres | Primary endpoints:  
• Safety  
• Determination of MTD  
Secondary endpoints: preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity | • FPCD: Q1 2017  
• Data anticipated: 2022 |
## MEDI7247 (PBD ADC mAb)

### Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I | Relapsed/Refractory Haematological Malignancies | 228      | First-time-in-human Phase 1, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects | • Primary endpoint: safety  
• Secondary endpoints: Pharmacokinetics, immunogenicity and anti-tumour activity | FPCD: Q2 2017  
Data anticipated: 2020 |
## MEDI9197 (TLR7/8 agonist)

### Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I | Advanced solid tumour malignancies readily accessible for injection | 135 | Dose-escalation phase  
  • MEDI9197 IT  
  • MEDI9197 IT + Imfinzi  
  • MEDI9197 IT + Imfinzi + palliative radiation | Primary endpoints:  
  • Safety  
  • Determination of MTD  
  • Secondary endpoints include:  
  – Objective response, disease control and duration of response  
  – Intratumoural and systemic PK and PD profiles/relationships | FPCD: Q4 2015  
  Data anticipated: 2020 |

**NCT02556463**

- Global trial – three countries

- MEDI9197 IT
- MEDI9197 IT + Imfinzi
- MEDI9197 IT + Imfinzi + palliative radiation
# MEDI9447 (CD73 mAb) + Imfinzi (PD-L1 mAb)

## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | Advanced malignancies    | 188      | Dose-escalation phase
  - MEDI9447 IV
  - MEDI9447 IV + Imfinzi IV  | Primary endpoints:  
  - Safety  
  - Determination of MTD  | US and Australian trial centres
  Dose expansion phase
  - MEDI9447 IV recommended dose  
  - MEDI9447 IV recommended dose + Imfinzi IV |  
  Secondary endpoints include preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity  | • FPCD: Q3 2015  
• Data anticipated: 2021 |
| NCT02503774 |                          |          |                                                                      |                                                                           |                                               |

**NCT02503774**

- **Phase I**
- **Population:** Advanced malignancies
- **Patients:** 188
- **Design:**
  - Dose-escalation phase
    - MEDI9447 IV
    - MEDI9447 IV + Imfinzi IV
  - Dose expansion phase
    - MEDI9447 IV recommended dose
    - MEDI9447 IV recommended dose + Imfinzi IV
- **Endpoints:**
  - Safety
  - Determination of MTD
  - Secondary endpoints include preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity
- **Status:**
  - FPCD: Q3 2015
  - Data anticipated: 2021
## Cancer

<table>
<thead>
<tr>
<th>Trial</th>
<th>Compound</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I NCT01284231 Partnered</td>
<td>Anti-CEA BiTE mAb (MEDI-565)</td>
<td>Adults with gastrointestinal (GI) adenocarcinoma with no available standard or curative treatments Refractory pancreatic, colorectal and gastro-oesophageal cancers</td>
<td>51 max</td>
<td>• Dose-escalation (3+3), IV • Dose expansion trial, IV</td>
<td>• MTD and safety profile</td>
<td>• FPCD: Q1 2011 • LPCD Q3 2014 • Data readout: Q1 2015</td>
</tr>
<tr>
<td>Phase I NCT01577745</td>
<td>Anti-DLL4 mAb (MEDI0639)</td>
<td>Adults with advanced solid tumours including SCLC</td>
<td>25</td>
<td>• Dose-escalation trial (3+3); IV</td>
<td>• MTD and safety profile</td>
<td>• FPCD: Q2 2012 • LPCD: Q2 2015 • Data readout: Q4 2015</td>
</tr>
</tbody>
</table>
# MEDI0382 (GLP-1-glucagon)

## Diabetes

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;NCT02394314 Completed</td>
<td>Healthy adult subjects</td>
<td>64</td>
<td>• SAD SC administration&lt;br&gt;• Germany</td>
<td>• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination</td>
<td>• FPCD: Q1 2015&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Data readout: Q4 2015</td>
</tr>
<tr>
<td><strong>Phase II</strong>&lt;br&gt;NCT02548585 Completed</td>
<td>Adults with type-2 diabetes</td>
<td>113</td>
<td>• MAD SC administration&lt;br&gt;• Germany</td>
<td>• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination&lt;br&gt;• Efficacy: MMT glucose AUC, HbA1c, fructosamine and body weight loss</td>
<td>• FPCD: Q1 2016&lt;br&gt;• LPCD: Q1 2017&lt;br&gt;• Data readout: Q1 2017</td>
</tr>
<tr>
<td><strong>Phase II</strong>&lt;br&gt;NCT03244800</td>
<td>Adults with type-2 diabetes</td>
<td>63</td>
<td>• ARM1: MEDI0382 SC or placebo&lt;br&gt;• ARM2: MEDI0382 SC or placebo&lt;br&gt;• Germany</td>
<td>• Efficacy: MMT glucose AUC, body weight loss, HbA1c, fasting plasma glucose&lt;br&gt;• Safety profile in terms of adverse events (AE), heart rate, blood pressure, vital signs, ECG, lab variables</td>
<td>• FPCD: Q3 2017&lt;br&gt;• Data anticipated: H1 2018</td>
</tr>
<tr>
<td><strong>Phase II</strong>&lt;br&gt;NCT03235050</td>
<td>Overweight and Obese subjects with type-2 diabetes</td>
<td>750</td>
<td>• ARM1: MEDI0382 low dose SC + metformin&lt;br&gt;• ARM2: MEDI0382 mid dose SC + metformin&lt;br&gt;• ARM3: MEDI0382 high dose SC + metformin&lt;br&gt;• ARM4: placebo SC + metformin&lt;br&gt;• ARM5: liraglutide SC + metformin&lt;br&gt;• US, Canada, Bulgaria, Czech Rep, Germany, Mexico, Russia, Slovakia</td>
<td>• Efficacy; HbA1c, body weight loss&lt;br&gt;• Percentage of subjects achieving weight loss of ≥5% and ≥10%&lt;br&gt;• Proportion of subjects rescued or discontinued for lack of glycaemic control&lt;br&gt;• PK and immunogenicity</td>
<td>• FPCD: Q3 2017&lt;br&gt;• Data anticipated: 2020</td>
</tr>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;NCT03235375</td>
<td>Adults with renal impairment</td>
<td>40</td>
<td>• ARM1: Subjects with CrCl &lt;20ml/min MEDI082 SC&lt;br&gt;• ARM2: Subjects with CrCl 20-30ml/min MEDI0382 SC&lt;br&gt;• ARM3: Subjects with CrCl &gt;90ml/min MEDI0382 SC</td>
<td>• PK, safety, tolerability and immunogenicity</td>
<td>• FPCD: Q3 2017&lt;br&gt;• Data anticipated: H1 2018</td>
</tr>
</tbody>
</table>
# MEDI0382 (GLP-1-glucagon)

## Diabetes

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy adult subjects</td>
<td>22</td>
<td>• Open label, one sequence, cross-over MEDI0382 with warfarin &amp; esmolol • US</td>
<td>• Effect of MEDI0382 on PK &amp; PD of warfarin &amp; esmolol • Safety profile • Immunogenicity</td>
<td>FPCD Q4 2017</td>
</tr>
<tr>
<td>NCT03347968</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>Healthy adult subjects</td>
<td>24</td>
<td>• Open label, cross-over, two period • Single dose MEDI0382 formulation 2 SC • Single dose MEDI0382 formulation 3 SC • US</td>
<td>• PK • Safety profile • Immunogenicity</td>
<td>FPCD Q4 2017</td>
</tr>
<tr>
<td>NCT03341013</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Biologics

### Cardiovascular & metabolic diseases

<table>
<thead>
<tr>
<th>Trial</th>
<th>Compound</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase IIa</td>
<td>rhLCAT MEDI6012</td>
<td>Adults with stable coronary artery disease (CAD) and low High-density lipoprotein (HDL)</td>
<td>56</td>
<td>SAD in stable CAD patients</td>
<td>Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, immunogenicity and physical examination</td>
<td>FPCD: Q4 2015, LPCD: Q2 2016, Data readout: Q4 2016</td>
</tr>
<tr>
<td>Phase IIa</td>
<td>NCT03004638</td>
<td>Adults with Stable Atherosclerotic Cardiovascular Disease (ACD)</td>
<td>32</td>
<td>MAD in stable ACD patients</td>
<td>Safety profile in terms of adverse events (AE), vital signs, ECG, lab variables, Changes in baseline adjusted post dose HDL-C, HDL-CE, and CE AUC, PK, immunogenicity, Apolipoprotein A,LDL, and Apolipoprotein B</td>
<td>FPCD: Q1 2017, Data readout: Q4 2017</td>
</tr>
<tr>
<td>Phase I</td>
<td>MEDI5884 Cholesterol modulation</td>
<td>Healthy Volunteers</td>
<td>64</td>
<td>SAD SC administration</td>
<td>Safety profile in terms of adverse events (AE), vital signs, ECG, lab variables, Changes in HDL-C over time</td>
<td>FPCD Q1 2017, LPCD Q3 2017, Data anticipated: H2 2018</td>
</tr>
<tr>
<td>Phase IIa</td>
<td>NCT03351738</td>
<td>Adults With Stable Coronary Heart Disease (CHD)</td>
<td>120</td>
<td>MEDI5884 (5 dose cohorts) vs Placebo in stable CHD patients</td>
<td>Safety profile in terms of adverse events (AE), vital signs, ECG, lab variables, Changes in HDL-C over time, PK, immunogenicity, and Apolipoprotein B</td>
<td>FPCD Q4 2017, Data anticipated: 2019</td>
</tr>
</tbody>
</table>
# MEDI3506 (IL-33 mAb)

## COPD

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase I (Combined SAD / MAD)</strong></td>
<td>SAD: Healthy subjects with mild atopy</td>
<td>SAD: 56</td>
<td>SAD:  • 7 sequential placebo-controlled single dose cohorts (active N=6 / placebo N = 2 within each cohort)  • Dose levels: 1mg SC, 3 mg SC, 10 mg SC, 30 mg SC, 100 mg SC, 300 mg SC and 300 mg IV</td>
<td>Safety and tolerability</td>
<td><strong>FPCD</strong>: Q2 2017  <strong>LPCD</strong>: Q3 2018  Data anticipated: 2019</td>
</tr>
<tr>
<td>NCT03096795</td>
<td>MAD: COPD</td>
<td>MAD: 24</td>
<td>MAD:  • 3 sequential placebo-controlled multiple dosing cohorts (active N=6 / placebo N = 2 within each cohort)  • Dose levels: 30 mg SC, 100 mg SC and 300 mg SC</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Approved medicines**

- **Oncology**
  - Late-stage development
  - Early development - IMED

- **Respiratory**
  - Early development - MedImmune

- **Other**
# MEDI7836 (IL-13 mAb)

## Asthma

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>32</td>
<td>• Arm 1: 30mg MEDI7836 (6) or placebo (2) as a single SC dose&lt;br&gt;• Arm 2: 105mg MEDI7836 (6) or placebo (2) as a single SC dose&lt;br&gt;• Arm 3: 300mg MEDI7836 (6) or placebo (2) as a single SC dose&lt;br&gt;• Arm 4: 600mg MEDI7836 (6) or placebo (2) as a single SC dose</td>
<td>• Safety and tolerability</td>
<td>• FPCD: Q1 2015&lt;br&gt;• LPCD: Q3 2015&lt;br&gt;• Data readout: Q1 2016</td>
</tr>
<tr>
<td>NCT02388347</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Approved medicines
Late-stage development
Early development - IMED
Early development - MedImmune
MEDI0700 - AMG 570 (Anti-B7RP-1 mAb/BAFF)  
Systemic lupus erythematosus (SLE)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase Ia</td>
<td>Healthy subjects</td>
<td>48</td>
<td>Single Ascending Dose</td>
<td>Safety and tolerability</td>
<td>FPCD: Q1 2016</td>
</tr>
<tr>
<td>NCT02618967</td>
<td></td>
<td></td>
<td>Arm 1: MEDI0700 administered as single SC dose</td>
<td>PK/PD</td>
<td>Data anticipated: H2 2018</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Arm 2: Dose levels of Placebo administered as single SC dose</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## MEDI1814 (amyloid beta mAb)

### Alzheimer’s disease

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Alzheimer’s disease &amp; healthy elderly</td>
<td>121</td>
<td>• SAD &amp; MAD  &lt;br&gt; • Up to 10 IV cohorts are planned vs placebo &lt;br&gt; • 2 SC cohorts are planned vs placebo &lt;br&gt; US only</td>
<td>• Safety, tolerability</td>
<td>• FPCD: Q2 2014 &lt;br&gt; • LPCD: Q2 2016 &lt;br&gt; • Data readout: Q4 2016</td>
</tr>
<tr>
<td>NCT02036645</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Approved medicines**

- **Oncology**
  - Late-stage development
  - Early development - IMED

- **CVMD**
  - Respiratory
  - Other
## MEDI5872 - AMG 557 (B7RP-1 mAb)

Systemic lupus erythematosus (SLE)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IIa      | Primary Sjögren's syndrome                       | 42       | • Arm 1: MEDI5872 210mg SC QW for 3 weeks and then Q2W for 9 weeks     | • Safety and tolerability  
                  | NCT02334306                                      |          | Arm 2: placebo SC QW for 3 weeks and then Q2W for 9 weeks             | • Change in the ESSDAI score from baseline to Day 99 | FPCD: Q3 2015  
                  | Partnered                                        |          | Global trial – five countries                                         |                                                                            | Data anticipated: H2 2018 |
| Phase I        | SLE and lupus related inflammatory arthritis     | 20       | Dose escalation trial:                                                | • Safety and tolerability  
                  | NCT01683695                                      |          | • Arm 1: MEDI5872 SC                                                  | • Lupus Arthritis Response Rate | FPCD: Q2 2012  
                  | Partnered Completed                              |          | • Arm 2: placebo SC                                                   |                                                                            | LPCD: Q4 2015  
                  |                                                  |          | Global trial – eight countries                                      |                                                                            | Data readout: Q2 2016 |

---

**Approved medicines**

**Late-stage development**

**Early development - IMED**

**Early development - MedImmune**

---

**Other**

---

**Respiratory**

---

**CVMD**

---

**Oncology**

---

---
## MEDI7352 (NGF TNF Bispecific)
### Osteoarthritis pain

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I | Painful osteoarthritis of the knee | 160      | • SAD & MAD
• Up to 10 IV cohorts are planned vs placebo
• 2 SC cohorts are planned vs placebo
Europe only | • Safety, tolerability, PK, PD     | FPCD: Q1 2016
Data anticipated: H1 2018 |
# MEDI9314 (IL-4Ra mAb)

## Atopic dermatitis

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I | Healthy subjects | 44 | • Arm 1: 45mg MEDI9314 (4) or placebo (2) as a single SC dose  
• Arm 2: 150mg MEDI9314 (4) or placebo (2) as a single SC dose  
• Arm 3: 300mg MEDI9314 (6) or placebo (2) as a single SC dose  
• Arm 4: MEDI9314 (6) or placebo (2) as a single IV dose  
• Arm 5: 300mg MEDI9314 (6) or placebo (2) as a single SC dose (Japanese subjects)  
• Arm 6: 450mg MEDI9314 (6) or placebo (2) as a single IV dose | • Safety and tolerability  
• Pharmacokinetic and immunogenicity profile | • FPPD: Q1 2016  
• LPCD: Q4 2016  
• Data readout: Q4 2016 |
## Other biomarkers

### Autoimmunity

<table>
<thead>
<tr>
<th>Trial</th>
<th>Compound</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II/III| Inebilizumab     | Adults with Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders | 212      | Arm 1: inebilizumab 500mg IV  
Arm 2: placebo IV  
Open-label extension 300mg Global trial – 26 Countries | Primary: Time to attack  
Secondary: Attack rate, safety and tolerability | NCT02200770  
• FPCD: Q1 2015  
• Data anticipated: 2023 |
| Phase I     | Anti-CD40L (MEDI4920) | Healthy adults                           | 56       | Arm 1: 3mg MEDI4920 (2) or placebo (1) as a single IV dose  
Arm 2: 10mg MEDI4920 (2) or placebo (1) as a single IV dose  
Arm 3: 3mg MEDI4920 (3) or placebo (2) as a single IV dose  
Arm 4: 100mg MEDI4920 (8) or placebo (2) as a single IV dose  
Arm 5: 300mg MEDI4920 (8) or placebo (2) as a single IV dose  
Arm 7: 2000mg MEDI4920 (8) or placebo (2) as a single IV dose | Safety, tolerability, and pharmacokinetics, anti-drug antibody, inhibition of T-cell dependent antibody response | NCT02151110  
• FPCD: Q2 2014  
• LPCD: Q4 2015  
• Data readout: Q2 2016 |
| Phase Ib    | Anti-ILT7 (MEDI7734) | Adults with adult-onset rheumatoid arthritis | 54       | Cohort 1: 10 subjects randomised in a 4:1 ratio to receive 75 mg MEDI4920 (8) or placebo (2) as a single IV dose administered over at least 30 minutes Q2W  
Cohort 2: 14 subjects randomised in a 5:2 ratio to receive 500 mg MEDI4920 (10) or placebo (4) as a single IV dose administered over at least 60 minutes Q2W  
Cohort 3: 16 subjects randomised in a 3:1 ratio to receive 1500 mg MEDI4920 (12) or placebo (4) as a single IV dose administered over at least 90 minutes Q2W,  
Cohort 4: 14 subjects randomised in a 5:2 ratio to receive 1000 mg MEDI4920 (10) or placebo (4) as a single IV dose administered over at least 90 minutes Q2W | Safety, tolerability, and pharmacokinetics, anti-drug antibody, inhibition of T-cell dependent antibody response | NCT02780388  
• FPCD: Q2 2016  
• LPCD: Q2 2018  
• Data anticipated: H2 2018 |
| Phase I     | Anti-ILT7        | Patients with Type I Interferon-Mediated Autoimmune Diseases | 36       | Arm 1: 1mg MEDI7734 (3) or placebo (1) as a single SC dose  
Arm 2: 5mg MEDI7734 (6) or placebo (2) as a single SC dose  
Arm 3: 15mg MEDI7734 (6) or placebo (2) as a single SC dose  
Arm 4: 50mg MEDI7734 (6) or placebo (2) as a single SC dose  
Arm 5: 150mg MEDI7734 (6) or placebo (2) as a single SC dose | Safety, tolerability  
Pharmacokinetics and pharmacodynamics | NCT02780674  
• FPCD Q3 2016  
• Data anticipated: H2 2018 |
## Other biologics

### Infections

<table>
<thead>
<tr>
<th>Trial</th>
<th>Compound</th>
<th>Population</th>
<th>Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase II</strong></td>
<td><strong>EudraCT 2014-001097-34</strong></td>
<td>Anti-Staph AT (MEDI4893)</td>
<td>Intubated ICU 285</td>
<td>• Placebo-controlled, single-dose, dose-ranging • Route of administration: intravenous</td>
<td>• Efficacy and safety</td>
<td>• FPCD: Q4 2014 • Data anticipated: 2019</td>
</tr>
<tr>
<td>Phase IIb</td>
<td><strong>NCT02878330</strong> Anti-Respiratory Syncytial Virus mAb-YTE (MEDI8897)</td>
<td>29-35 WK GA infants 1,500</td>
<td>• Randomised, double-blind, placebo-controlled trial • Route of administration: IM</td>
<td>• Safety and efficacy</td>
<td>• FPCD: Q4 2016 • Data anticipated: H2 2018</td>
<td></td>
</tr>
<tr>
<td>Phase Ib/IIa</td>
<td><strong>NCT02290340</strong> Completed</td>
<td>32-35 WK GA infants 89</td>
<td>• Randomised, double-blind, placebo-controlled, dose-escalation trial • Route of administration: IM</td>
<td>• Evaluate Safety, tolerability, PK and ADA</td>
<td>• FPCD: Q1 2015 • LPCD: Q3 2015 • Data readout: Q3 2016</td>
<td></td>
</tr>
<tr>
<td>Phase Ia</td>
<td><strong>NCT02114268</strong> Completed</td>
<td>Healthy adults 136</td>
<td>• Randomised, double-blind, placebo-controlled, Dose-escalation trial • Route of administration: IV and IM</td>
<td>• Evaluate Safety, tolerability, PK and ADA</td>
<td>• FPCD: Q2 2014 • LPCD: Q2 2014 • Data readout: Q2 2015</td>
<td></td>
</tr>
<tr>
<td>Phase Ib/IIa</td>
<td><strong>NCT02603952</strong> Completed</td>
<td>Adults 126</td>
<td>• Randomised, partial double-blind, single dose, active-controlled, dose ranging trial • Route of administration: intravenous</td>
<td>• Evaluate safety in adults with acute, uncomplicated Influenza</td>
<td>• FPCD: Q4 2015 • LPCD: Q4 2016 • Data readout: Q4 2016</td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td><strong>NCT02350751</strong> Completed</td>
<td>Healthy adults 40</td>
<td>• Double-blind, single-dose, placebo-controlled, dose-escalation trial • Route of administration: intravenous</td>
<td>• Evaluate the safety and pharmacokinetics</td>
<td>• FPCD: Q1 2015 • LPCD: Q1 2015 • Data readout: Q2 2015</td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td><strong>NCT02255760</strong> Completed</td>
<td>Anti-Pseudomonas A mAb (MEDI3902) Healthy adults 56</td>
<td>• Randomised, double-blind, placebo-controlled, dose-escalation trial • Route of administration: intravenous</td>
<td>• Evaluate the safety, tolerability, and pharmacokinetics</td>
<td>• FPCD: Q3 2014 • LPCD: Q1 2015 • Data readout: Q2 2015</td>
<td></td>
</tr>
<tr>
<td>Phase II</td>
<td><strong>NCT02696902</strong> Completed</td>
<td>Intubated ICU 429</td>
<td>• Placebo-controlled, single-dose, dose-ranging • Route of administration: intravenous</td>
<td>• Efficacy and safety</td>
<td>• FPCD: Q2 2016 • Data anticipated: 2021</td>
<td></td>
</tr>
</tbody>
</table>
Clinical trials appendix
Full-Year and Q4 2017 Results update