Clinical trials appendix
Q1 2016 update
The following information about AstraZeneca clinical trials in Phases I-IV has been created with selected information from 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 March 2016, 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.

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.
## List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AEs</td>
<td>Adverse Events</td>
</tr>
<tr>
<td>ASA</td>
<td>Acetylsalicylic Acid</td>
</tr>
<tr>
<td>BID</td>
<td>Twice Daily</td>
</tr>
<tr>
<td>CE</td>
<td>Clinically Evaluable</td>
</tr>
<tr>
<td>cMITT</td>
<td>Clinical Modified Intent-To-Treat population</td>
</tr>
<tr>
<td>DLT</td>
<td>Dose Limiting Toxicity</td>
</tr>
<tr>
<td>FEV</td>
<td>Forced Expiratory Volume</td>
</tr>
<tr>
<td>FPD</td>
<td>First Patient Dosed</td>
</tr>
<tr>
<td>HIF-PHI</td>
<td>Hypoxia-inducible factor prolyl hydroxylase inhibitor</td>
</tr>
<tr>
<td>ICS</td>
<td>Inhaled Corticosteroid</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>Intra-venous</td>
</tr>
<tr>
<td>LABA</td>
<td>Long Acting Beta Agonist</td>
</tr>
<tr>
<td>LAMA</td>
<td>Long Acting Muscarinic Agonist</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 trial</td>
</tr>
<tr>
<td>MDI</td>
<td>Metered Dose Inhaler</td>
</tr>
<tr>
<td>MITT</td>
<td>Modified Intent-To-Treat population</td>
</tr>
<tr>
<td>mMITT</td>
<td>Microbiological Modified Intent-To-Treat population</td>
</tr>
<tr>
<td>MTD</td>
<td>Maximum Tolerated Dose</td>
</tr>
<tr>
<td>MTX</td>
<td>Methotrexate</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>PARP</td>
<td>Poly ADP ribose polymerase</td>
</tr>
<tr>
<td>PFS</td>
<td>Progression Free Survival</td>
</tr>
<tr>
<td>Q2W</td>
<td>Every Other Week</td>
</tr>
<tr>
<td>Q3W</td>
<td>Every Three Weeks</td>
</tr>
<tr>
<td>Q4W</td>
<td>Every Four Weeks</td>
</tr>
<tr>
<td>Q8W</td>
<td>Every Eight Weeks</td>
</tr>
<tr>
<td>QD</td>
<td>Once Daily</td>
</tr>
<tr>
<td>SAD</td>
<td>Single Ascending Dose trial</td>
</tr>
<tr>
<td>SC</td>
<td>Sub-cutaneous</td>
</tr>
<tr>
<td>TiD</td>
<td>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>
### Movement since Q4 2015

<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>AZD5634</td>
<td>inhaled ENaC cystic fibrosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDI9314</td>
<td>IL4R atopic dermatitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDJ0700</td>
<td>BAFF/TRP1 systemic lupus erythematosus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD5178</td>
<td>FLAP CAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDI7352</td>
<td>NGF/TNF bispecific mAb osteoarthritis pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional indications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>durvalumab* + monalizumab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PD-L1 + NKG2a mAb solid tumours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>durvalumab* + MEDI9447</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PD-L1 + CD73 mAb solid tumours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDI3902</td>
<td>Psl/PcrV pseudomonas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MEDI4166</td>
<td>PCSK9/GLP-1 diabetes/cardiovascular</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD3293* BACE Alz</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beta secretase inhibitor Alzheimer’s disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD5312* androgen receptor inhibitor solid tumours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD9835</td>
<td>PI3 kinase alpha inhibitor solid tumours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD8999</td>
<td>MABA COPD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional indications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inebilizumab (MEDI-551* + rituximab)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD19 mAb + CD20 mAb haematological malignancies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>tremelimumab* DETERMINE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTLA-4 mAb mesothelioma abrilumab*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alpha(4)beta(7) mAb Crohn’s disease / ulcerative colitis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZD9291 + durvalumab* CAURAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥2nd-+line advanced EGFRm T790M NSCLC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brillinta/Brilique SOCRATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P2Y12 receptor antagonist outcomes trial in patients with stroke or TIA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NMEs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bevespi Aerospace (PT003 GFF) PINNACLE LABA/LAMA COPD</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Collaboration

*Registrational Phase II/III study
Q1 2016 New Molecular Entity (NME)\(^1\) Pipeline

### Phase I
*3 New Molecular Entities*

<table>
<thead>
<tr>
<th>Small molecule</th>
<th>Large molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADZ1459</td>
<td>MEDI3566 EDF609PM BLE</td>
</tr>
<tr>
<td>ADZ2994</td>
<td>MEDI3904 S1F45</td>
</tr>
<tr>
<td>ADZ6718</td>
<td>MEDI3566 S646</td>
</tr>
</tbody>
</table>

### Phase II
*25 New Molecular Entities*

<table>
<thead>
<tr>
<th>Small molecule</th>
<th>Large molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADZ19916</td>
<td>MEDI2174 TDF718 solid tumours</td>
</tr>
<tr>
<td>ADZ2047</td>
<td>MEDI2174 solid tumours</td>
</tr>
<tr>
<td>ADZ7037</td>
<td>MEDI2174 solid tumours</td>
</tr>
<tr>
<td>ADZ2078</td>
<td>MEDI2174 solid tumours</td>
</tr>
<tr>
<td>ADZ7029</td>
<td>MEDI2174 solid tumours</td>
</tr>
<tr>
<td>ADZ20475</td>
<td>MEDI2174 solid tumours</td>
</tr>
<tr>
<td>ADZ20785</td>
<td>MEDI2174 solid tumours</td>
</tr>
<tr>
<td>ADZ20786</td>
<td>MEDI2174 solid tumours</td>
</tr>
</tbody>
</table>

### Phase III
*10 New Molecular Entities*

<table>
<thead>
<tr>
<th>Small molecule</th>
<th>Large molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZD9451</td>
<td>MEDI2174 solid tumours</td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Small molecule</th>
<th>Large molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZD9451</td>
<td>MEDI2174 solid tumours</td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></td>
</tr>
<tr>
<td>MEDI2174 solid tumours</td>
<td></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)  
   # In collaboration; \(^2\) Registrational P2/3 study;  
   MEDI-550 does not count toward late-stage NME totals (submitted to EMEA December 2015)
# Q1 2016 Lifecycle Management (LCM) Pipeline

**Phase I**
- **Small molecule**
  - Oncology
  - Infectious Disease (VIRUS)
  - NASH
  - Inflammation
  - Pain
  - RIA
  - CVMD
  - Infection, Neuroscience, Gastrointestinal

**Phase II**
- **Small molecule**
  - Oncology
  - RIA
  - CVMD
  - Infection, Neuroscience, Gastrointestinal

**Phase III**
- **Small molecule**
  - Lympara (lymphoma)
  - Pain
  - CVMD
  - Oncology

**Applications Under Review**
- **Small molecule**
  - Oncology
  - CVMD
  - Infection, Neuroscience, Gastrointestinal

---

**Oncology Combinations**

<table>
<thead>
<tr>
<th>Phase I</th>
<th>3 Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lympara (lymphoma)</td>
<td>Pain</td>
</tr>
<tr>
<td>Pain</td>
<td>CVMD</td>
</tr>
<tr>
<td>CVMD</td>
<td>Infection, Neuroscience, Gastrointestinal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phase II</th>
<th>9 Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lympara (lymphoma)</td>
<td>Pain</td>
</tr>
<tr>
<td>Pain</td>
<td>CVMD</td>
</tr>
<tr>
<td>CVMD</td>
<td>Infection, Neuroscience, Gastrointestinal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phase III</th>
<th>24 Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lympara (lymphoma)</td>
<td>Pain</td>
</tr>
<tr>
<td>Pain</td>
<td>CVMD</td>
</tr>
<tr>
<td>CVMD</td>
<td>Infection, Neuroscience, Gastrointestinal</td>
</tr>
</tbody>
</table>

---

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

# In collaboration; ¹ Registrational P2/3 study; ¤ Medimmune-sponsored study in collaboration with Innate Pharma

---
Lifecycle management (new uses of existing medicines)
### Symbicort (ICS/LABA)

**Mild asthma**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III**  
 SYGMA1  
 NCT02149199 | Patients in need of GINA step-2 treatment | N = 3,750 | • Arm 1: Symbicort Turbuhaler 160/4.5 μg ‘as needed’ + Placebo Pulmicort Turbuhaler 200 μg bid  
• Arm 2: Pulmicort 200 μg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler ‘as needed’  
• Arm 3: I terbutaline Turbuhaler 0.4 mg ‘as needed’ + placebo Pulmicort 200 μg Turbuhaler bid | • Well-controlled asthma weeks  
• Time to first severe asthma exacerbation  
• Time to first moderate or severe asthma exacerbation  
• Average change from baseline in pre-dose FEV₁ | • FPD: Q4 2014  
• LPCD: 2017  
• Estimated completion: 2017  
• Estimated top-line results: 2017 |
| **Phase III**  
 SYGMA2  
 NCT02224157 | Patients in need of GINA step-2 treatment | N = 4,114* | • Arm 1: Symbicort Turbuhaler 160/4.5 μg ‘as needed’ + Placebo Pulmicort Turbuhaler 200 μg bid  
• Arm 2: Pulmicort 200 μg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler ‘as needed’  
• Arm 3: Terbutaline Turbuhaler 0.4 mg ‘as needed’ + placebo Pulmicort 200 μg Turbuhaler bid | • Annual severe asthma exacerbation rate  
• Time to first severe asthma exacerbation  
• Average change from baseline in pre-dose FEV₁  
• Time to trial specific asthma related discontinuation | • FPD: Q1 2015  
• LPCD: 2017  
• Estimated completion: 2017  
• Estimated top-line results: 2017 |

* There will be a blinded review for event rate which means that the final number of patients is uncertain until this review has taken place.
**Eklira/Tudorza (LAMA)**

**Chronic Obstructive Pulmonary Disease (COPD)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IV   | Patients with COPD | N = 224 | • Arm 1: Aclidinium bromide 400 μg  
• Arm 2: Placebo to aclidinium bromide 400 μg  
Global trial – five countries | • Change from baseline in Overall E-RS Total score (i.e. score over the whole 8 weeks trial period)  
• 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 | • FPD: Q1 2015  
• LPCD: Q3 2015  
• Clinically completed  
• Top-line results released Q1 2016  
• Estimated completion date: Q2 2016 |
| ASCENT     | Patients with moderate to very severe COPD | N = 4,000 | • Arm 1: Aclidinium bromide 400 μg  
• Arm 2: Placebo to aclidinium bromide 400 μg  
Global trial – two countries | • 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.  
• 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 | • FPD: Q4 2013  
• LPCD: H2 2016  
• Estimated completion date: 2018 |
| NCT02153489 | Patients with stable moderate and severe COPD | N = 30 | • Arm 1: Aclidinium bromide 400 μg  
• Arm 2: Placebo to Aclidinium bromide 400 μg  
Local trial – one country | • Change from baseline in normalised FEV₁, Week 3. FEV₁ over the 24-hour period (AUC0-24) will be measured following morning administration  
• Adverse events. Week 5. A follow up telephone call will be made 14 days after the last trial drug administration (for completed patients) or premature discontinuation visit (when applicable) to record adverse events | • FPD: Q2 2014  
• LPCD: Q1 2015  
• Top-line results: Q4 2015  
• Estimated completion date: H2 2016 |
### Duaklir (LAMA/LABA)

**Chronic Obstructive Pulmonary Disease (COPD)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IV          | Patients with moderate to COPD         | N = 268            | • Arm 1: Aclidinium/formoterol FDC 400/12 μg                            | • Change from baseline in trough Functional Residual capacity after 4 weeks of treatment  
• Change from baseline in Endurance Time (ET) during constant work rate cycle ergometry to symptom limitation at 75% of Wmax after 8 weeks of treatment  
• Percentage of inactive patients (<6000 steps per day) after 8 weeks on treatment                                                                 | • FPD: Q2 2015  
• LPCD: Q2 2016  
• Estimated completion date: H2 2016                                                                 |
**Daliresp (oral PDE4 inhibitor)**

**Chronic Obstructive Pulmonary Disease (COPD)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase IV</td>
<td>RESPOND</td>
<td>COPD</td>
<td>N = 2,354</td>
<td>52W, randomised, DB with Daliresp 500µg OD vs placebo, in COPD on top of ICS/LABA</td>
<td>Rate of moderate or severe COPD exacerbations per subject per year</td>
</tr>
<tr>
<td>NCT01443845</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Completed: Q1 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Estimated results: H2 2016</td>
</tr>
<tr>
<td>Phase IV</td>
<td>OPTIMIZE</td>
<td>COPD</td>
<td>N = 1,323</td>
<td>12W, randomised, DB to evaluate tolerability and PK of Daliresp 500 µg OD with an up-titration regimen during the first 4Ws, including an open label down-titration evaluating tolerability and PK of 250µg Roflumilast OD in subjects not tolerating 500 µg OD</td>
<td>Percentage of participants prematurely discontinuing study treatment for any reason during the main period</td>
</tr>
<tr>
<td>NCT02165826</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Completed: Q3 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Estimated results: H2 2016</td>
</tr>
<tr>
<td>Phase IIIb</td>
<td>ROBERT</td>
<td>COPD</td>
<td>N = 158</td>
<td>16W, randomised, placebo-controlled, DB, parallel-group trial to assess the anti-inflammatory effects of Roflumilast in COPD</td>
<td>Number of inflammatory cells CD8+ in bronchial biopsy tissue specimen (submucosa) measured at randomisation and at the end of the intervention period</td>
</tr>
<tr>
<td>NCT01509877</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Completed: Q1 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Estimated results: H2 2016</td>
</tr>
</tbody>
</table>
### Zurampic (lesinurad) (SURI, URAT1 inhibitor)

#### Gout

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III</td>
<td>RDEA594-306 CLEAR Extension</td>
<td>N = 717</td>
<td>Zurampic 200 or 400 mg QD All patients: SOC allopurinol QD Protocol amended Oct 2015: All patients to receive Zurampic treatment dose of 200 mg QD in combination with their allopurinol</td>
<td>• Assess the long-term efficacy and safety of Zurampic in combination with allopurinol</td>
<td>• FPD: Q1 2013 • Trial ongoing • LPCD: 2017</td>
</tr>
<tr>
<td></td>
<td>NCT01808131</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase III</td>
<td>RDEA594-307 CRYSTAL Extension</td>
<td>N = 196</td>
<td>Zurampic 200 or 400 mg QD All patients: febuxostat 80 mg QD Protocol amended Oct 2015: All patients to receive Zurampic treatment dose of 200 mg QD in combination with their febuxostat</td>
<td>• Assess the long-term efficacy and safety of Zurampic in combination with febuxostat</td>
<td>• FPD: Q1 2013 • Trial ongoing • LPCD: 2017</td>
</tr>
<tr>
<td></td>
<td>NCT01808144</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase II</td>
<td>RDEA594-203 Open-label Extension</td>
<td>N = 87</td>
<td>Zurampic 200, 400, or 600 mg QD All patients: SOC allopurinol QD Protocol amended Oct 2015: All patients to receive Zurampic treatment dose of 200 mg QD in combination with their allopurinol</td>
<td>• Assess the long-term efficacy and safety of Zurampic in combination with allopurinol</td>
<td>• FPD: Q1 2011 • Trial ongoing • LPCD: H2 2016</td>
</tr>
<tr>
<td></td>
<td>NCT01001338</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Lesinurad/allopurinol FDC (SURI, URAT1 inhibitor/XOI inhibitor)

### Gout

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I RDEA594-501 Randomised, Open-label, cross-over, relative bioavailability</td>
<td>Healthy Male Subjects</td>
<td>N = 124</td>
<td>Cohort 1: cross-over, rel. BA Tx. 1: lesinurad/allopurinol 200/300 FDC Tx. 2: coadministered lesinurad 200mg + allopurinol 300mg</td>
<td>• Assess the bioavailability of lesinurad/allopurinol 200/300 FDC and lesinurad/allopurinol 200/200 FDC tablets relative to coadministered lesinurad and allopurinol tablets in healthy adult male subjects</td>
<td>• FPD: Q4 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cohort 2: cross-over, Food Effect, BA Tx. 1: lesinurad/allopurinol 200/300 FDC (fasted) Tx. 2: lesinurad/allopurinol 200/300 FDC (fed – high fat meal)</td>
<td>• To assess the effect of a high fat/high calorie meal on the pharmacokinetics of lesinurad/allopurinol 200/300 FDC tablets in healthy adult male subjects</td>
<td>• LPCD: Q2 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cohort 3: cross-over, rel. BA Tx. 1: lesinurad/allopurinol 200/200 FDC Tx. 2: coadministered lesinurad 200mg + allopurinol 200mg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Bevespi Aerosphere (PT003, LABA/LAMA)**

**Chronic Obstructive Pulmonary Disease (COPD)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III PINNACLE 1**
NCT01854645 | Moderate to very severe COPD | N = 2,103 | Treatment (24-week Treatment Period)  
• Arm 1: GFF MDI (Bevespi Aerosphere) 14.4/9.6 μg BiD  
• Arm 2: GP MDI (PT001) 14.4 μg BiD  
• Arm 3: FF MDI (PT005) 9.6 μg BiD  
• Arm 4: Open-label Tiotropium bromide inhalation powder 18 μg QD  
• Arm 5: Placebo MDI BiD  
Multicentre, randomised, double-blind, parallel-group, chronic dosing, placebo- and active-controlled  
Estimated time from FSFV to DBL is approximately 21 months. US, Australia, New Zealand | • Change from baseline in morning pre-dose trough FEV₁ | • FPD: Q2 2013  
• LPCD: Q3 2014  
• Top-line results: Q1 2015*  
* Clinically completed |
| **Phase III PINNACLE 2**
NCT01854658 | Moderate to very severe COPD | N = 1,618 | Treatment (24-week Treatment Period)  
• Arm 1: GFF MDI (Bevespi Aerosphere) 14.4/9.6 μg BiD  
• Arm 2: GP MDI (PT001) 14.4 μg BiD  
• Arm 3: FF MDI (PT005) 9.6 μg BiD  
• Arm 4: Placebo MDI BiD  
Multicentre, randomised, double-blind, parallel-group, chronic dosing and placebo-controlled  
Estimated time from FSFV to DBL is approximately 20 months. US | • Change from baseline in morning pre-dose trough FEV₁ | • FPD: Q3 2013  
• LPCD: Q3 2014  
• Top-line results: Q2 2015*  
* Clinically completed |
| **Phase III PINNACLE 3**
NCT01970878 | Moderate to very severe COPD | N = 850 | Treatment (28-week Treatment Period)  
• Arm 1: GFF MDI (Bevespi Aerosphere) 14.4/9.6 μg BiD  
• Arm 2: GP MDI (PT001) 14.4 μg BiD  
• Arm 3: FF MDI (PT005) 9.6 μg BiD  
• Arm 4: Open-label Tiotropium bromide inhalation powder QD  
Multi-centre, randomised, double-blind, parallel-group and active-controlled  
Estimated time from FSFV to DBL is approximately 16 months. US, Australia, New Zealand | • Overall safety, tolerability and efficacy | • FPD: Q4 2013  
• LPCD: Q3 2014  
• Top-line results: Q2 2015*  
* Clinically completed |
# Bevespi Aerosphere (PT003, LABA/LAMA)

## Chronic Obstructive Pulmonary Disease (COPD)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase IIIb (Dose Indicator trial) NCT02268396</td>
<td>Moderate to severe COPD</td>
<td>N = 150</td>
<td>Treatment (5- to 6-week Treatment Period)</td>
<td>• Percentage of devices where number of actuations as counted at the end of the trial using dose indicator reading is consistent (± 20 actuations) with number of actuations reported by subject</td>
<td>• FPD: Q4 2014&lt;br&gt;• LPCD: Q4 2014&lt;br&gt;• Top-line results: Q1 2015*&lt;br&gt;* Clinically completed</td>
</tr>
<tr>
<td>Phase IIIb (24 Hr Lung Function Placebo) NCT02347085</td>
<td>Moderate to severe COPD</td>
<td>N = 40</td>
<td>Treatments (8-week Treatment Period)</td>
<td>• FEV1 AUC0-24 on Day 29</td>
<td>• FPD: Q1 2015&lt;br&gt;• LPCD: Q1 2015&lt;br&gt;• Top-line results: Q3 2015&lt;br&gt;* Clinically completed</td>
</tr>
<tr>
<td>Phase IIIb (24 Hr Lung Function Active) NCT02347072</td>
<td>Moderate to severe COPD</td>
<td>N = 80</td>
<td>Treatments (12-week Treatment Period)</td>
<td>• Change from morning pre-dose trough FEV1, GFF 14.4/9.6 µg with Aerochamber Plus VHC relative to GFF14.4µg w/o Aerochamber Plus VHC on Day 8&lt;br&gt;PK parameters at all doses will include Cmax, AUC0-12, AUC0-t, tmax, Other PD/PK parameters may be calculated, as appropriate</td>
<td>• FPD: Q2 2015&lt;br&gt;• LPCD: Q1 2016&lt;br&gt;• Estimated top-line results: Q2 2016</td>
</tr>
<tr>
<td>Phase III (Spacer trial) NCT02454959</td>
<td>Moderate to severe COPD</td>
<td>N = 60</td>
<td>Treatments (2 week treatment period)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Bevespi Aerosphere (PT003, LABA/LAMA)

Chronic Obstructive Pulmonary Disease (COPD)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design (G = glycopyrronium, F = formoterol fumarate)</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III           | Moderate to very severe COPD | N = 1,614          | Treatments (24-week Treatment Period)                | • For the US/China approach, the primary endpoint will be the change from baseline in morning pre-dose trough FEV₁ at Week 24 of treatment  
  • For the EU and Hybrid approaches, the primary endpoint will be the change from baseline in morning pre-dose trough FEV₁ over 24 weeks of treatment  
  • For the Japan approach, the primary endpoint will be the change from baseline in morning pre-dose trough FEV₁ over Weeks 12 to 24 of treatment  
  • TDI score (co-primary endpoint for EU and Hybrid) [Time Frame: Over 24 Weeks] | NCT02343458  
  • Right Ventricular End Diastolic Volume Index (RVEDVi) measured at 2 hours post-dose on Day 8 | FPD: Q2 2015  
  • LPCD: Q2 2016  
  • Estimated top-line results: 2017 |
| (Asia Pacific trial) |                    |                    |                                                      |                                                                           |                                     |
| NCT02343458         |                    |                    |                                                      |                                                                           |                                     |
| Phase IIb           | Moderate to severe COPD | N = 40             | Treatments (5-week Treatment Period)                | • Right Ventricular End Diastolic Volume Index (RVEDVi) measured at 2 hours post-dose on Day 8 | FPD: Q2 2016  
  • LPCD: H2 2016  
  • Estimated top-line results: 2017 |
| (CV trial)          |                    |                    |                                                      |                                                                           |                                     |
| NCT02685293         |                    |                    |                                                      |                                                                           |                                     |
# Brilinta/Brilique (ADP receptor antagonist)

## Cardiovascular

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III | **PEGASUS** | Patients with prior MI | N = 21,000 | • Arm 1: Brilinta/Brilique 90 mg BID  
• Arm 2: Brilinta/Brilique 60 mg BID  
• Arm 3: Placebo BID on a background of ASA  
Global trial – 31 countries | • Composite of CV death, non-fatal MI and non-fatal stroke | • FPD: Q4 2010  
• LPCD: Q4 2014  
• Completion date: Q4 2014 |
|             | **EUCLID** | Patients with PAD | N = 13,500 | • Arm 1: Brilinta/Brilique 90 mg BID  
• Arm 2: Clopidogrel 75 mg QD monotherapy trial  
Global trial – 28 countries | • Composite of CV death, non-fatal MI and ischemic stroke | • FPD: Q4 2012  
• LPCD: H2 2016  
• Estimated top-line results: H2 2016 |
|             | **THEMIS** | Patients with type-2 diabetes and coronary artery disease without a previous history of MI or stroke | N = 19,000 | • Arm 1: Brilinta/Brilique 60 mg BID  
• Arm 2: Placebo BID on a background of ASA if not contra indicated or not tolerated  
Global trial – 42 countries | • Composite of CV death, non-fatal MI and non-fatal stroke | • FPD: Q1 2014  
• LPCD: 2018  
• Estimated top-line results: 2018 |
| Phase III (BE) | **(BE)** | Japanese healthy volunteers | N = 36 | Single dose, Cross-Over  
• Arm 1: Brilinta/Brilique OD tablet 90 mg + 150 mL of water  
• Arm 2: Brilinta/Brilique OD tablet 90 mg without water  
• Arm 3: Brilinta/Brilique IR tablet (90 mg) + 200 mL of water  
Local trial – one country | • BE of ticagrelor Dispersible Tablet vs ticagrelor IR tablet | • FPD: Q2 2015  
• LPCD: Q3 2015  
• Completion date: Q3 2015  
• Top-line results: Q4 2015 |
### Brilinta/Brilique (ADP receptor antagonist)

#### Cardiovascular

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III (BE) NCT02400333</td>
<td>Caucasian healthy volunteers</td>
<td>N = 36</td>
<td>Single dose. Cross-Over</td>
<td>• BA/BE of Brilinta/Brilique Dispersible Tablet vs Brilinta/Brilique IR tablet</td>
<td>• FPD: Q2 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 1: Brilinta/Brilique OD tablet 90 mg + 200 ml of water</td>
<td>• Number of days with pain due to Sickle Cell Disease</td>
<td>• LPCD: Q3 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 2: Brilinta/Brilique OD tablet 90 mg without water</td>
<td></td>
<td>• Completion date: Q3 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 3: Brilinta/Brilique OD tablet 90 mg (suspended in water) via nasogastric tube</td>
<td></td>
<td>• Top-line results: Q4 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 4: Brilinta/Brilique IR tablet 90 mg + 200 mL of water</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Local trial – one country</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase II HESTIA2 NCT02462298</td>
<td>Patients with sickle disease</td>
<td>N = 90</td>
<td>• Arm 1: Brilinta/Brilique 10 mg BID</td>
<td></td>
<td>• FPD: Q3 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 2: Brilinta/Brilique 45 mg BID</td>
<td></td>
<td>• LPCD: H2 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 3: Placebo BID</td>
<td></td>
<td>• Estimated completion date: H2 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Global trial – eight countries</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Onglyza (DPP-4 inhibitor)

## Type-2 Diabetes

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III  | Type-2 diabetes mellitus | N = 444 | • Arm 1: Onglyza 5 mg QD + insulin or Onglyza 5 mg QD + Met + Placebo QD + insulin or Placebo  
   • Arm 2: QD + insulin + Met  
   Trial in China | Primary:  
   • Change from baseline in HbA1C at 24 weeks  
   Secondary:  
   • Change from baseline at 24 weeks in 120-minute postprandial plasma glucose (PPG) in response to a meal tolerance | • FPD: Q3 2014  
• LPCD: Q1 2016  
• Estimated top-line results: Q2 2016 |
| Phase III  | Type-2 diabetes mellitus | N = 639 | • Arm 1: Onglyza 5 mg + Met (500 mg with titration)  
   • Arm 2: Onglyza 5 mg + Placebo  
   • Arm 3: Met (500 mg with titration) + Placebo  
   Trial in China | Primary:  
   • The change in HbA1c from baseline to week 24 (prior to rescue)  
   Secondary:  
   • The proportion of subjects achieving a therapeutic glycaemic response at week 24 (prior to rescue) defined as HbA1c <7.0% | • FPD: Q1 2015  
• LPCD: H2 2016  
• Estimated top-line results: 2017 |
# Farxiga/Forxiga (SGLT2 inhibitor)

## Diabetes

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase IV** | Japanese patients with type-2 diabetes with inadequate glycemic control on insulin | N = 266 | • Arm 1: Forxiga 5mg  
• Arm 2: Placebo  
Japan trial | • Change from baseline in HbA1c at week 16  
• 1 year LT data | **FPD: Q2 2014**  
**LPCD: Q4 2015**  
**Top-line Results: Q1 2016**  
**Estimated completion date: Q2 2016** |
| **Phase III/IV DECLARE** | Type-2 diabetes mellitus with high risk for CV event | N = 17,276 | • Arm 1: Farxiga/Forxiga 10 mg QD + standard of care therapy  
• Arm 2: Placebo + standard of care therapy for type-2 Diabetes  
Global trial – 33 countries | • Time to first event included in the composite endpoint of CV death, MI or ischemic stroke | **FPD: Q2 2013**  
**LPCD: 2019**  
**Estimated top-line results: 2019**  
**Estimated completion date: 2019** |
| **Phase III DERIVE** | Asian subjects with type-2 diabetes who have inadequate glycemic control on insulin | N = 273 | • Arm 1: Forxiga 10 mg QD for 24 weeks + background Insulin  
• Arm 2: Placebo QD for 24 weeks + background Insulin  
Asian trial – three countries | • Change from baseline in HbA1c at week 24 | **FPD: Q1 2014**  
**LPCD: Q1 2016**  
**Estimated top-line results: Q2 2016**  
**Estimated completion date: Q2 2016** |
| **Phase III DEPICT 1** | Patients with type-2 diabetes and moderate renal impairment | N = 302 | • Arm 1: Farxiga/Forxiga 10 mg QD for 24 weeks  
• Arm 2: Placebo 10 mg QD for 24 weeks  
Global trial – 5 countries | • Change from baseline in HbA1c at Week 24 | **FPD: Q2 2015**  
**LPCD: 2017**  
**Estimated top-line results: 2017**  
**Estimated completion date: 2017** |
| **Phase III DEPICT 2** | Type-1 diabetes mellitus | N = 768 | • Arm 1: Farxiga/Forxiga 5 mg QD 52 weeks + insulin  
• Arm 2: Farxiga/Forxiga 10 mg QD 52 weeks + insulin  
• Arm 3: Placebo QD 52 weeks + insulin  
Global trial – 17 countries | Primary:  
• Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at Week 24 | **FPD: Q4 2014**  
**LPCD: 2017**  
**Estimated top-line results: 2017** |
| **Phase III DEPICT 2** | Type-1 diabetes mellitus | N = 768 | • Arm 1: Farxiga/Forxiga 5 mg QD 52 weeks + insulin  
• Arm 2: Farxiga/Forxiga 10 mg QD 52 weeks + insulin  
• Arm 3: Placebo QD 52 weeks + insulin  
Global trial – 14 countries | Primary:  
• Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at Week 24 | **FPD: Q3 2015**  
**LPCD: 2017**  
**Estimated top-line results: 2018** |
# Saxagliptin/dapagliflozin (DPP-4/SGLT2 inhibitors)

## Diabetes

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III</td>
<td>Type-2 diabetes mellitus</td>
<td>N = 420</td>
<td>• Arm 1: Saxagliptin 5 mg + dapagliflozin 10 mg + Met IR/XR&lt;br&gt;• Arm 2: Sitagliptin 100 mg + Met IR/XR&lt;br&gt;Global trial – six countries</td>
<td>Primary:&lt;br&gt;• Mean change from baseline in HbA1C at week 24&lt;br&gt;Secondary:&lt;br&gt;• The proportion of subjects achieving a therapeutic glycemic response at week 24 defined as HbA1C&lt;7%&lt;br&gt;• Mean change in total body weight at week 24</td>
<td>FPD: Q1 2015&lt;br&gt;LPCD: H2 2016&lt;br&gt;Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td>Phase III</td>
<td>Type-2 diabetes mellitus</td>
<td>N = 440</td>
<td>• Arm 1: Saxagliptin 5 mg + dapagliflozin 10 mg + Met IR/XR&lt;br&gt;• Arm 2: Glimeperide 1-6 mg + Met IR/XR&lt;br&gt;Global trial – 10 countries</td>
<td>Primary:&lt;br&gt;• Mean change from baseline in HbA1C at week 52&lt;br&gt;Secondary:&lt;br&gt;• Mean change from baseline in total body weight at week 52&lt;br&gt;• The proportion of subjects achieving a therapeutic glycemic response at week 52 defined as HbA1C&lt;7.0%</td>
<td>FPD: Q3 2015&lt;br&gt;LPCD: 2017&lt;br&gt;Estimated top-line results: 2017</td>
</tr>
<tr>
<td>Phase III</td>
<td>Type-2 diabetes mellitus</td>
<td>N = 598</td>
<td>• Arm 1: Saxagliptin 5 mg + dapagliflozin 10 mg + Met IR/XR&lt;br&gt;with or without SU&lt;br&gt;• Arm 2: Insulin glargine + Met IR/XR with or without SU&lt;br&gt;Global trial – 12 countries</td>
<td>Primary:&lt;br&gt;• Mean change from baseline in HbA1C at week 24&lt;br&gt;Secondary:&lt;br&gt;• Mean change in total body weight at week 24&lt;br&gt;• The proportion of subjects with confirmed hypoglycemia at week 24</td>
<td>FPD: Q4 2015&lt;br&gt;LPCD: 2017&lt;br&gt;Estimated top-line results: 2017</td>
</tr>
<tr>
<td>Phase III</td>
<td>Type-2 diabetes mellitus</td>
<td>N = 900</td>
<td>• Arm 1: Saxagliptin 5 mg + dapagliflozin 5 mg + Met IR/XR&lt;br&gt;• Arm 2: Dapagliflozin 5 mg + placebo + Met IR/XR&lt;br&gt;• Arm 3: Saxagliptin 5 mg + placebo + Met IR/XR&lt;br&gt;Global trial – six countries</td>
<td>Primary:&lt;br&gt;• Mean change from baseline in HbA1C at week 24&lt;br&gt;Secondary:&lt;br&gt;• The proportion of subjects achieving a therapeutic glycemic response at week 24 defined as HbA1C&lt;7%&lt;br&gt;• Mean change in fasting plasma glucose at 24 weeks</td>
<td>FPD: Q1 2016&lt;br&gt;LPCD: 2017&lt;br&gt;Estimated top-line results: 2017</td>
</tr>
</tbody>
</table>
### Bydureon (GLP-1 receptor agonist)

#### Type-2 Diabetes

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of 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>N = 14,000</td>
<td>♦ Arm 1: Bydureon once weekly 2mg SC&lt;br&gt;♦ Arm 2: Placebo&lt;br&gt;On a background of standard of care medication, different degree of CV risk&lt;br&gt;Global trial</td>
<td>♦ 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: 2017&lt;br&gt;♦ Estimated completion: 2018</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;DURATION-NEO 1&lt;br&gt;NCT01652716&lt;br&gt;Partnered</td>
<td>Type-2 diabetes</td>
<td>N = 375</td>
<td>♦ Arm 1: Bydureon BiD SC (autoinjector)&lt;br&gt;♦ Arm 2: Bydureon weekly suspension SC (autoinjector)&lt;br&gt;On a background of diet &amp; exercise alone or with stable regimen of oral antidiabetics&lt;br&gt;US only</td>
<td>♦ Change in HbA1c from baseline at 28 weeks</td>
<td>♦ FPD: Q1 2013&lt;br&gt;♦ Completed: Q3 2014</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;DURATION-NEO 2&lt;br&gt;NCT01652729&lt;br&gt;Partnered</td>
<td>Type-2 diabetes</td>
<td>N = 360</td>
<td>♦ Arm 1: Sitagliptin&lt;br&gt;♦ Arm 2: Bydureon weekly suspension SC (autoinjector)&lt;br&gt;♦ Arm 3: Placebo&lt;br&gt;On a background of diet &amp; exercise alone or with stable regimen of oral antidiabetics&lt;br&gt;US only</td>
<td>♦ Change in HbA1c from baseline at 28 weeks</td>
<td>♦ FPD: Q1 2013&lt;br&gt;♦ Completed: Q3 2014</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;DURATION 7&lt;br&gt;NCT02229383</td>
<td>Type-2 diabetes</td>
<td>N = 440</td>
<td>♦ Arm 1: Bydureon once weekly 2 mg SC + Titrated Basal Insulin&lt;br&gt;♦ Arm 2: Placebo + Titrated Basal Insulin&lt;br&gt;Double-blind 1:1 randomisation&lt;br&gt;Background therapy with or without Metformin&lt;br&gt;Global trial</td>
<td>♦ Change in HbA1c from baseline at 28 weeks</td>
<td>♦ FPD: Q3 2014&lt;br&gt;♦ LPCD: H2 2016&lt;br&gt;♦ Estimated completion: H2 2016</td>
</tr>
</tbody>
</table>
Bydureon (GLP-1 receptor agonist)
Type-2 Diabetes

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III DURATION 8 NCT02229396 | Type-2 diabetes | N = 660 | • Arm 1: Bydureon once weekly 2 mg SC  
• Arm 2: Dapagliflozin 10 mg  
• Arm 3: Bydureon once weekly 2 mg SC + dapagliflozin 10 mg  
    Double-blind 1:1:1 randomisation  
    Background therapy with Metformin 1500 mg/day up to 2 months prior to screening  
    Global trial | • Change in HbA1c from baseline at 28 weeks | • FPD: Q3 2014  
• LPCD: 2017  
• Estimated completion:  
  H2 2016 - 28-week data  
  2017 - 52-week data  
  2018 - 104-week data |
# Epanova (omega-3 carboxylic acids)

## Hypertriglyceridaemia

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III</strong></td>
<td><strong>Japanese Long-term Safety</strong>&lt;br&gt;NCT02463071</td>
<td>Japanese patients with hypertriglyceridemia&lt;br&gt;N = 375</td>
<td>• Epanova 2 g and 4 g vs. Placebo (after meal) daily for 52 weeks&lt;br&gt;Global trial – one country</td>
<td>• Safety in Japanese patients&lt;br&gt;• % change in triglycerides</td>
<td>• FPD: Q2 2015&lt;br&gt;• LPCD: 2017&lt;br&gt;• Estimated top-line results: 2017</td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td><strong>EVOLVE II</strong>&lt;br&gt;NCT02009865</td>
<td>Severe hyper-triglyceridaemia&lt;br&gt;N = 162</td>
<td>• Arm 1: Epanova 2g QD&lt;br&gt;• Arm 2: Placebo (olive oil)&lt;br&gt;Global trial – seven countries</td>
<td>• Change in serum triglycerides over 12 weeks</td>
<td>• FPD: Q4 2013&lt;br&gt;• LPCD: Q4 2014&lt;br&gt;• Completed: Q4 2015</td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td><strong>STRENGTH (CVOT)</strong>&lt;br&gt;NCT02104817</td>
<td>Patients with hypertriglyceridaemia and high CVD risk&lt;br&gt;N = 13,000</td>
<td>• Arm 1: Epanova 4g QD + statin&lt;br&gt;• Arm 2: Placebo (corn oil) + statin&lt;br&gt;Global trial – 22 countries</td>
<td>• Composite of MACE</td>
<td>• FPD: Q4 2014&lt;br&gt;• Estimated top-line results: 2019</td>
</tr>
<tr>
<td><strong>Phase II</strong></td>
<td><strong>EFFECT I</strong>&lt;br&gt;NCT02354976</td>
<td>Overweight patients with hypertriglyceridemia&lt;br&gt;N = 75</td>
<td>• Epanova 4 g vs. Placebo vs. Fenofibrate 200 mg daily for 12 weeks&lt;br&gt;Global trial – one country</td>
<td>• Reduction in liver fat content (%) at the end of 12 weeks compared to placebo&lt;br&gt;• Reduction in liver fat content (%) at the end of 12 weeks compared to fenofibrate</td>
<td>• FPD: Q3 2015&lt;br&gt;• LPCD: Q2 2016&lt;br&gt;• Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td><strong>Phase II</strong></td>
<td><strong>EFFECT II</strong>&lt;br&gt;NCT02279407</td>
<td>Type-2 DM&lt;br&gt;Liver fat &gt;5.5%&lt;br&gt;N = 80</td>
<td>• Arm 1: Epanova 4g QD&lt;br&gt;• Arm 2: Placebo (olive oil)&lt;br&gt;• Arm 3: Epanova 4gm + dapaglifozin 10 mg QD&lt;br&gt;• Arm 4: Dapaglifozin 10 mg&lt;br&gt;Local trial – one country</td>
<td>• Reduction in liver fat content (%) at the end of 12 weeks</td>
<td>• FPD: Q4 2015&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Estimated top-line results: Q2 2016</td>
</tr>
<tr>
<td><strong>Phase I</strong></td>
<td><strong>PRECISE</strong>&lt;br&gt;NCT02370537</td>
<td>Pancreatic Exocrine Insufficiency (PEI) in patients with type-2 diabetes&lt;br&gt;N = 66</td>
<td>• Arm 1: Epanova 4g single dose&lt;br&gt;• Arm 2: Omacor 4 g single dose&lt;br&gt;Global trial – six countries in Europe</td>
<td>• Presence of Pancreatic Exocrine Insufficiency (PEI), Pharmacokinetics of Epanova and Omacor following a single oral dose in patients with different degrees of PEI</td>
<td>• FPD: Q1 2015&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Estimated top-line results: Q2 2016</td>
</tr>
</tbody>
</table>
# Epanova (omega-3 carboxylic acids)

## Hypertriglyceridaemia

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy volunteers</td>
<td>N = 40 Part A</td>
<td>- Arm 1: D1400147 4g</td>
<td>- Rate and extent of absorption of omega-3-carboxylic acids following single-dose oral administration of test formulations A, B and C and reference formulation (Epanova®) under fed and fasted condition, by assessment of AUC, AUC(0-72) and Cmax</td>
<td>FPD: Q1 2015, LPCD: Q3 2015, Completed: Q4 2015</td>
</tr>
<tr>
<td>NCT02359045</td>
<td>N = 42 Part B</td>
<td></td>
<td>- Arm 2: D14000136 4g</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Arm 3: D14000137 4g</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Arm 4: Epanova 4g</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Local trial – one country</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 1: D1400147 4g</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 2: D14000136 4g</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 3: D14000137 4g</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 4: Epanova 4g</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>Healthy male volunteers</td>
<td>N = 42</td>
<td>- Epanova 4 g X 3 separate occasions (fasting, before meal, and after meal)</td>
<td>- Effect of food timing (fasting, before meal, and after meal) on pharmacokinetics (AUC, Cmax, AUC0-72)</td>
<td>FPD: Q1 2015, LPCD: Q2 2015, Completed: Q4 2015</td>
</tr>
<tr>
<td>Japanese food interaction</td>
<td></td>
<td></td>
<td>Local trial – one country</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02372344</td>
<td></td>
<td></td>
<td>• Arm 1: (Japanese): Epanova 2g vs. Placebo QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 2: (Japanese): Epanova 4g vs Placebo QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 3: (Caucasian): Epanova 4g vs Placebo</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Local trial – one country</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 1: (Japanese): Epanova 2g vs. Placebo QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 2: (Japanese): Epanova 4g vs Placebo QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 3: (Caucasian): Epanova 4g vs Placebo</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAD/MAD</td>
<td></td>
<td></td>
<td>- Arm 2: Epanova 4g →Epanova 4g QD</td>
<td>- Safety/tolerability profile</td>
<td></td>
</tr>
<tr>
<td>NCT02209766</td>
<td></td>
<td></td>
<td>- Arm 3: Epanova 2g →Lovaza 4g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Arm 4: Lovaza 4g →Epanova 2g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Local trial – one country</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 1: Epanova 2g →Lovaza 4g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 2: Epanova 4g →Epanova 4g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 3: Epanova 2g →Lovaza 4g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 4: Lovaza 4g →Epanova 2g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>Patients with a history of pancreatitis</td>
<td>N = 16</td>
<td>- Arm 1: Epanova 4g →Lovaza 4g QD</td>
<td>- Plasma concentration vs. time curve (AUC0-1)</td>
<td>FPD: Q3 2014, LPCD: Q2 2015, Top-line results: Q4 2015</td>
</tr>
<tr>
<td>NCT02189252</td>
<td></td>
<td></td>
<td>- Arm 2: Lovaza 4g →Epanova 4 g QD</td>
<td>- (Time Frame: 0 to 24 hours (AUC0-24))</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Arm 3: Epanova 2g →Lovaza 4g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Arm 4: Lovaza 4g →Epanova 2g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Global trial – two countries</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 1: Epanova 4g →Lovaza 4g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 2: Lovaza 4g →Epanova 4 g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 3: Epanova 2g →Lovaza 4g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 4: Lovaza 4g →Epanova 2g QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Faslodex (oestrogen receptor antagonist)

## Breast cancer - metastatic

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III   | Postmenopausal women with HR+ locally advanced or metastatic breast cancer, who have not previously been treated with any hormonal therapy (1L) | N ~ 450            | Arm 1: Faslodex 500 mg monthly IM + an additional dose on d14 (+ oral placebo)  
Arm 2: Arimidex 1 mg (+ placebo injection)  
Global trial – 21 countries | PFS  
OS is a secondary endpoint                                                   |                       | FPD: Q4 2012  
LPCD: Q3 2014  
Estimated top-line results: Q2 2016                                           |

- **FALCON**
- **NCT01602380**
# Lynparza (PARP inhibitor)

## Ovarian cancer and other solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III SOLO-2** Partnered | PSR BRCAm ovarian cancer | N = 264 | • Arm 1: Lynparza tablets 300 mg BiD as maintenance therapy until progression  
• Arm 2: placebo tablets BiD  
Global trial | • PFS  
• OS secondary endpoint | • FPD: Q3 2013  
• LPCD: Q4 2014  
• Estimated top-line results: H2 2016 |
| **Phase III SOLO-1** Partnered | 1L maintenance BRCAm ovarian cancer | N = 344 | • Arm 1: Lynparza tablets 300 mg BiD maintenance therapy for 2 years or until disease progression  
• Arm 2: placebo  
Global trial | • PFS  
• OS secondary endpoint | • FPD: Q3 2013  
• LPCD: Q1 2015  
• Estimated top-line results: 2017 |
| **Phase III SOLO-3** Partnered | PSR gBRCAm ovarian cancer 3L+ Line | N = 411 | • Arm 1: Lynparza 300 mg BiD to progression  
• Arm 2: Physician’s choice (single agent chemotherapy)  
Global trial | • PFS  
• OS secondary endpoint | • FPD: Q1 2015  
• LPCD: 2017  
• Estimated top-line results: 2018 |
| **Phase III GOLD** Partnered | 2L gastric cancer (all patients with a co-primary sub population) | N = 525 | • Arm 1: paclitaxel + Lynparza until progression  
• Arm 2: paclitaxel + placebo  
Lynparza dose 100mg BiD throughout paclitaxel dose cycle & 300 mg BiD post cycle  
Asian trial | • OS | • FPD: Q3 2013  
• LPCD: Q4 2015  
• Estimated top-line results: Q2 2016 |
# Lynparza (PARP inhibitor)

## Solid Tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</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>
</tbody>
</table>
| OlympiAD         | BRCAm metastatic breast cancer | N = 310            | • Arm 1: Lynparza 300 mg BID, continuous to progression  
• Arm 2: Physician’s choice: capcitabine 2500 mg/m2 x 14 q 21  
vinorelbine 30 mg/m2 d 1, 8 q 21  
eribulin 1.4 mg/m2 d 1, 8 q 21 to progression  
Global trial | • PFS  
• Secondary endpoint: OS | • FPD: Q2 2014  
• LPCD: Q4 2015  
• Estimated top-line results: H2 2016 |
|                   |                    |                    |                                                                      |                                                     |                             |
| Phase III         | BRCAm adjuvant breast cancer | N = 1,500          | • Arm 1: Lynparza 300 mg BID  
12 month duration  
• Arm 2: Placebo 12 month duration  
Global trial partnership with BIG and NCI/NRG | • Invasive Disease Free Survival (IDFS)  
• Secondary endpoint: Distant Disease Free Survival and OS | • FPD: Q2 2014  
• LPCD: 2018  
• Estimated top-line results: 2020 |
| POLO              | Pancreas gBRCA     | N = 145            | • Arm 1: Lynparza tablets 300 mg twice daily as maintenance therapy until progression.  
• Arm 2: placebo tablets BID  
Global trial | • Primary endpoint: PFS  
• Secondary endpoint: OS | • FPD: Q1 2015  
• LPCD: 2017  
• Estimated top-line results: 2018 |
|                   |                    |                    |                                                                      |                                                     |                             |
| Phase II          | Metastatic castration resistant prostate CA | N = 140            | • Arm 1: Lynparza 300mg BID + abiraterone  
• Arm 2: Placebo + abiraterone  
Global trial | • Radiologic PFS | • FPD: Q3 2014  
• LPCD: Q3 2015  
• Estimated top-line results: H2 2016 |
### Tagrisso (Highly selective, irreversible EGFR TKI)

**Non-small cell lung cancer (NSCLC)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III AURA3</strong>&lt;br&gt;NCT02151981</td>
<td>Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M</td>
<td>N = 410</td>
<td>- Arm 1: Tagrisso 80mg QD&lt;br&gt;- Arm 2: pemetrexed 500mg/m² + carboplatin AUC5 or pemetrexed 500mg/m² + cisplatin 75mg/m² (2:1 randomisation) Global trial</td>
<td>- PFS&lt;br&gt;- OS is a secondary endpoint&lt;br&gt;- PFS&lt;br&gt;- OS and QoL as secondary endpoints</td>
<td>FPD: Q3 2014&lt;br&gt;Enrolment complete&lt;br&gt;Estimated primary completion: H2 2016</td>
</tr>
<tr>
<td><strong>Phase III FLAURA</strong>&lt;br&gt;NCT02296125</td>
<td>Advanced EGFRm NSCLC 1L</td>
<td>N = 530</td>
<td>- Arm 1: Tagrisso 80mg&lt;br&gt;- Arm 2: erlotinib 150mg or <em>Iressa</em> 250 mg (dealers choice); 1:1 randomisation Global trial</td>
<td>- PFS&lt;br&gt;- OS and QoL as secondary endpoints</td>
<td>FPD: Q1 2015&lt;br&gt;Estimated completion: 2017</td>
</tr>
<tr>
<td><strong>Phase III ADAURA</strong>&lt;br&gt;NCT02511106</td>
<td>Adjuvant EGFRm NSCLC</td>
<td>N = 700</td>
<td>- Arm 1: Tagrisso 80mg QD following complete tumour resection, with or without chemotherapy&lt;br&gt;- Arm 2: Placebo Global trial</td>
<td>- DFS&lt;br&gt;- DFS Rate, OS, OS Rate, QoL</td>
<td>FPD: Q4 2015&lt;br&gt;Estimated completion: 2022</td>
</tr>
<tr>
<td><strong>Phase III CAURAL</strong>&lt;br&gt;NCT02454933</td>
<td>Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M</td>
<td>N = 350</td>
<td>- Arm 1: Tagrisso (80mg QD) + MEDI4736 (10mg/kg q2w (IV) infusion)&lt;br&gt;- Arm 2: Tagrisso (80mg QD) Global trial</td>
<td>- PFS&lt;br&gt;- ORR, OS, QoL as secondary endpoints</td>
<td>FPD: Q3 2015&lt;br&gt;Enrolment hold implemented in Q4 2015&lt;br&gt;Will not restart</td>
</tr>
<tr>
<td><strong>Phase II AURA17</strong>&lt;br&gt;NCT02442349</td>
<td>Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M</td>
<td>N = 175</td>
<td>Tagrisso 80 mg QD Asia Pacific Regional trial</td>
<td>- ORR&lt;br&gt;- PFS and OS secondary endpoints</td>
<td>FPD: Q3 2015&lt;br&gt;Enrolment complete&lt;br&gt;Estimated primary completion: Q2 2016</td>
</tr>
<tr>
<td><strong>Phase II AURA2</strong>&lt;br&gt;NCT02094261</td>
<td>Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M</td>
<td>N = 175</td>
<td>Tagrisso 80 mg QD Global trial</td>
<td>- ORR&lt;br&gt;- PFS and OS secondary endpoints</td>
<td>FPD: Q2 2014&lt;br&gt;Enrolment complete (N = 210)</td>
</tr>
<tr>
<td><strong>Phase II AURA</strong>&lt;br&gt;NCT01802632</td>
<td>Advanced EGFRm NSCLC TKI failure +/- primary resistance mutation T790M</td>
<td>N = 500</td>
<td>Dose escalation trial&lt;br&gt;- Ph II Extension cohort (T790M only) Tagrisso 80mg QD Global trial</td>
<td>Safety and tolerability&lt;br&gt;- ORR&lt;br&gt;- PFS and OS secondary endpoints</td>
<td>FPD: Q1 2013&lt;br&gt;Enrolment complete (N = 201 in extension portion)</td>
</tr>
</tbody>
</table>
## Tagrisso (Highly selective, irreversible EGFR TKI)

Non-small cell lung cancer (NSCLC)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase Ib TATTON NCT02143466</td>
<td>Advanced EGFRm NSCLC TKI failure</td>
<td>N ~ 90</td>
<td>• Arm 1: Tagrisso + MEDI4736&lt;br&gt;• Arm 2: Tagrisso + AZD6094&lt;br&gt;• Arm 3: Tagrisso + selumetinib&lt;br&gt;Global trial</td>
<td>• Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity</td>
<td>• FPD: Q3 2014&lt;br&gt;• Dose escalation completed&lt;br&gt;• Dose expansions ongoing&lt;br&gt;• Enrolment to durvalumab combo arms will not restart</td>
</tr>
<tr>
<td>Phase I BLOOM NCT02228369</td>
<td>EGFRm NSCLC, CNS disease</td>
<td>N = 47</td>
<td>• MAD&lt;br&gt;• Expansion in LM patients at RP2D with AZD3759&lt;br&gt;• Expansion in LM patients at 160mg with Tagrisso including cohort with T790M NSCLC&lt;br&gt;Global trial – four countries</td>
<td>• Safety and tolerability&lt;br&gt;• Preliminary anti-tumour activity</td>
<td>• FPD: Q4 2014&lt;br&gt;• Estimated primary completion: H2 2016</td>
</tr>
</tbody>
</table>
# Nexium

## Gastrointestinal

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III   | Seriously ill patients with at least one major risk factor for stress ulcer related bleeding (Stress Ulcer Prophylaxis) | N = 300 | • Arm 1: Nexium 40 mg bid intermittent iv infusions given for max. 14 days  
• Arm 2: Cimetidine 300 mg bolus iv infusion followed by continuous iv infusion 50mg/h for a maximum of 14 days  
China-only trial | • Clinically significant upper GI bleeding | • FPD: Q3 2014  
• LPCD: Q1 2016  
• Estimated completion: Q2 2016 |

- **NCT02157376**
Late-stage development
# Brodalumab (IL-17R mAb)

## Psoriasis

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III AMAGINE-1 NCT01708590 | Moderate to severe plaque psoriasis | N = 661 | - Arm 1: 210 mg brodalumab SC  
- Arm 2: 140 mg brodalumab SC  
- Arm 3: Placebo SC | - PASI at wk 12  
- Static physician’s global assessment (sPGA) at wk 12 | Completed - Partnered |
| Phase III AMAGINE-2 NCT01708603 | Moderate to severe plaque psoriasis | N = 1,800 | - Arm 1: 210 mg brodalumab SC  
- Arm 2: 140 mg brodalumab SC  
- Arm 3: 45 or 90 mg ustekinumab SC  
- Arm 4: Placebo SC | - PASI at wk 12  
- Static physician’s global assessment (sPGA) at wk 12 | Completed - Partnered |
| Phase III AMAGINE-3 NCT01708629 | Moderate to severe plaque psoriasis | N = 1,881 | - Arm 1: 210 mg brodalumab SC  
- Arm 2: 140 mg brodalumab SC  
- Arm 3: 45 or 90 mg ustekinumab SC  
- Arm 4: Placebo SC | - PASI at wk 12  
- Static physician’s global assessment (sPGA) at wk 12 | Completed - Partnered |
**PT009 (ICS/LABA)**

**Chronic Obstructive Pulmonary Disease (COPD)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design (G = Glycopyrronium, F = Formoterol fumarate)</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II          | Moderate to severe COPD     | N = 180            | • BFF MDI 320/9.6 μg BID  
• BFF MDI 160/9.6 μg BID  
• BFF MDI 80/9.6 μg BID  
• BD MDI 320 μg BID  
• FF MDI 9.6 μg BID  
Randomised, 4-period, 5-treatment incomplete-block and crossover  
Estimated time from FSFV to DBL is approximately 7 months. US | • Forced expiratory volume in 1 second area under the curve from 0 to 12 hours (FEV1 AUC0-12)  
• FPD: Q3 2014  
• LPCD: Q3 2014  
• Top-line results: Q2 2015*  
* Clinically completed |---------------------------------------------|
| (BFF Dose-ranging)| NCT02196077                |                    |                                                     |                                                                           |---------------------------------------------|

**Lifecycle management**

*Late-stage development*
- Early development - IMED
- Early development - MedImmune
## PT010 (LABA/LAMA/ICS)
### Chronic Obstructive Pulmonary Disease (COPD) & Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III (Long-term BMD and Ocular Safety)</td>
<td>Moderate to very severe COPD</td>
<td>N = 500</td>
<td>Treatments (52-week Treatment Period)</td>
<td>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</td>
<td>FSD: Q3 2015 &lt;br&gt; LPCD: H2 2016 &lt;br&gt; Estimated top-line results: 2017</td>
</tr>
<tr>
<td>NCT02536508</td>
<td></td>
<td></td>
<td>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</td>
<td>Ocular Sub-study Safety Endpoint: • Change from baseline in LOCS III at Week 52</td>
<td>FSD: Q3 2015 &lt;br&gt; LPCD: H2 2016 &lt;br&gt; Estimated top-line results: 2017</td>
</tr>
<tr>
<td>Phase III (Exacerbation trial) ETHOS</td>
<td>Moderate to very severe COPD</td>
<td>N = 8,000 (possible increase by 4,000 after blinded sample size re-assessment)</td>
<td>Treatments (1-year Treatment Period)</td>
<td>• Rate of moderate or severe COPD exacerbations &lt;br&gt; • Time to first moderate or severe COPD exacerbation</td>
<td>FPD: Q3 2015 &lt;br&gt; LPCD: 2017 &lt;br&gt; Estimated top-line results: 2018</td>
</tr>
<tr>
<td>NCT02465567</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FPD: Q3 2015 &lt;br&gt; LPCD: 2017 &lt;br&gt; Estimated top-line results: 2018</td>
</tr>
<tr>
<td>Phase III (Lung function trial) KRONOS</td>
<td>Moderate to very severe COPD</td>
<td>N = 1,800</td>
<td>Treatments (24-week Treatment Period)</td>
<td>Co-Primary Endpoints (EU): • FEV1 area under curve from 0 to 4 hours (AUC0-4) over 24 weeks (BGF MDI vs BFF MDI) &lt;br&gt; • Transition dyspnea index (TDI) focal score over 24 weeks (BGF MDI vs BFF MDI and BGF MDI vs GFF MDI) &lt;br&gt; Primary Endpoint (Japan): • Change from baseline in morning pre-dose trough FEV1 over 24 weeks. (BGF MDI vs BFF MDI) &lt;br&gt; Change from baseline in morning pre-dose trough FEV1 over 24 weeks. (BGF MDI vs BFF MDI)</td>
<td>FPD: Q3 2015 &lt;br&gt; LPCD: H2 2016 &lt;br&gt; Estimated top-line results: 2017</td>
</tr>
<tr>
<td>NCT02497001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FPD: Q3 2015 &lt;br&gt; LPCD: H2 2016 &lt;br&gt; Estimated top-line results: 2017</td>
</tr>
</tbody>
</table>
# PT010 (LABA/LAMA/ICS)

## Chronic Obstructive Pulmonary Disease (COPD) & Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II (BD Dose-ranging in Asthma) | Adult mild to moderate persistent asthma | N = 150 | • Arm 1: BD MDI 320 µg BID  
• Arm 2: BD MDI 160 µg BID  
• Arm 3: BD MDI 80 µg BID  
• Arm 4: BD MDI 40 µg BID  
• Arm 5: Placebo MDI BID  
Randomised, 4-period, 5-treatment incomplete-block and crossover  
Four week estimated time from FSFV to DBL is approximately 18 months. US | • Change from baseline in morning pre-dose trough forced expiratory volume in one second (FEV₁)  
• Mean evening pre-dose peak flow rate (PEFR)  
• Mean number of puffs of rescue Ventolin hydrofluoroalkane (HFA)  
• Asthma Control Questionnaire score | • FPD: Q2 2014  
• LPCD: Q1 2015  
• Top-line results: Q3 2015  
* Clinically completed |
| Phase II | Intermittent asthma/mild to moderate persistent asthma | N = 200 | Treatment (18-week Treatment Period)  
• GP MDI 28.8 µg BID  
• GP MDI 14.4 µg BID  
• GP MDI 7.2 µg BID  
• GP MDI 3.6 µg BID  
• SevereN® Diskus® 50µ BID  
• Placebo MDI  
Randomised, double-blind, chronic-dosing, placebo controlled, incomplete block, cross over, multi-centre, dose-ranging trial  
Estimated time from FSFV to DBL is approximately 11 months. US | • Peak change from baseline in FEV₁ within 3 hours post-dosing on Day 15 | • FPD: Q2 2015  
• LPCD: Q4 2015  
• Estimated top-line results: Q2 2016 |
## PT010 (LABA/LAMA/ICS)

### Chronic Obstructive Pulmonary Disease (COPD) & Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase I** (BGF PK trial)       | Healthy volunteers               | N = 72             | • Arm 1: BGF MDI 320/14.4/9.6 µg  
• Arm 2: BFF MDI (320/9.6 µg)  
• Arm 3: Symbicort Turbuhaler 400/12 µg  
Randomised, double-blind, single-dose, 3-period, 3-treatment and crossover  
Estimated time from FSFV to DBL is approximately three months. US  
  | • Overall safety  
• PK parameters AUC0-12 and Cmax | • FPD: Q3 2014  
• LPCD: Q3 2014  
• Top-line results: Q4 2014*  
* Clinically completed |
| **Phase I** (BGF PK in Japanese Subjects) | Japanese healthy volunteers | N = 20             | Treatment (2-week Treatment Period)  
• Arm 1: BGF MDI 320/14.4/9.6 µg  
• Arm 2: BGF MDI 160/14.4/9.6 µg  
• Arm 3: Placebo MDI  
Randomised, double-blind, placebo-controlled,  
2-period, ascending-dose and crossover  
Estimated time from FSFV to DBL is approximately eight weeks. Japan  
  | • Overall safety  
• PK parameters AUC0-12 and Cmax | • FPD: Q3 2014  
• LPCD: Q3 2014  
• Top-line results: Q4 2014*  
* Clinically completed |
| **Phase I** (GFF PK in Japanese Subjects) | Japanese healthy volunteers | N = 24             | Treatment (4-day Treatment Period)  
• Arm 1: GFF MDI 14.4/6 µg  
• Arm 2: GFF MDI 28.8/6 µg  
• Arm 2: GP MDI 14.4 µg  
• Arm 2: GP MDI 28.8 µg  
Randomised, double-blind, single-dose, 4-Period, 4-treatment and crossover  
Estimated time from FSFV to DBL is approximately 13 weeks. Japan  
  | • Overall safety  
• PK parameters AUC0-12 and Cmax | • FPD: Q3 2014  
• LPCD: Q3 2014  
• Top-line results: Q4 2014*  
* Clinically completed |
## Benralizumab (IL-5R mAb)

### Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III  | Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12 – 75yrs | N = 1,026 HD + ~200 MD | • Arm 1: 30 mg Q8w SC  
  • Arm 2: 30 mg Q4w SC  
  • Arm 3: Placebo SC  
  56-week trial Global trial – 11 countries | • Annual asthma exacerbation rate  
  • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM | FPD: Q4 2013  
  Estimated completion: Q2 2016 |
| CALIMA     |                                                                                                         |                    |                                                                        |                                                                           |                                                                      |
| NCT01914757|                                                                                                         |                    |                                                                        |                                                                           |                                                                      |
| Phase III  | Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA ± chronic OCS Age 12 – 75 yrs | N = 1,134          | • Arm 1: 30 mg Q8w SC  
  • Arm 2: 30 mg Q4w SC  
  • Arm 3: Placebo SC  
  48-week trial Global trial – 17 countries | • Annual asthma exacerbation rate  
  • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM | FPD: Q4 2013  
  Estimated completion: Q2 2016 |
| SIROCCO    |                                                                                                         |                    |                                                                        |                                                                           |                                                                      |
| NCT01928771|                                                                                                         |                    |                                                                        |                                                                           |                                                                      |
| Phase III  | Severe asthma, inadequately controlled on HD ICS plus long-acting β2 agonist and chronic oral corticosteroid therapy Age 18 – 75 yrs | N = 210            | • Arm 1: 30 mg Q8w SC  
  • Arm 2: 30 mg Q4w SC  
  • Arm 3: Placebo SC  
  46-week trial Global trial – 12 countries | • Reduction of oral corticosteroid dose  
  • Assessed pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM | FPD: Q3 2014  
  Estimated completion: H2 2016 |
| ZONDA      |                                                                                                         |                    |                                                                        |                                                                           |                                                                      |
| NCT02075255|                                                                                                         |                    |                                                                        |                                                                           |                                                                      |
## Benralizumab (IL-5R mAb)

### Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III</td>
<td>BISE</td>
<td>NCT02322775</td>
<td>Asthmatic with FEV1 (50-90% predicted) on low to medium dose inhaled corticosteroid Age 18 – 75 yrs</td>
<td>N = 200</td>
<td>• Arm 1: 30 mg Q4W SC&lt;br&gt;• Arm 2: 30 mg Q8W SC&lt;br&gt;• Arm 3: Placebo SC&lt;br&gt;12-week trial&lt;br&gt;Global trial – six countries</td>
</tr>
<tr>
<td>Phase III</td>
<td>BORA</td>
<td>NCT02258542</td>
<td>Severe asthma, inadequately controlled despite background controller medication, MD &amp; HD ICS + LABA ± chronic OCS Age 12 – 75yrs</td>
<td>N = 2,550</td>
<td>• Arm 1: 30 mg Q4W SC&lt;br&gt;• Arm 2: 30 mg Q6W SC*&lt;br&gt;• Arm 3: Placebo SC*&lt;br&gt;* Placebo administered at select interim visits to maintain blind between treatment arms</td>
</tr>
<tr>
<td>Phase III</td>
<td>GREGALE</td>
<td>NCT02417961</td>
<td>Severe asthma, inadequately controlled despite background controller medication, MD &amp; HD ICS + LABA ± chronic OCS Age 18 – 75yrs</td>
<td>N = 120</td>
<td>• Arm 1: 30 mg Q4W SC&lt;br&gt;28-week (adults)&lt;br&gt;Global trial – two countries</td>
</tr>
</tbody>
</table>
## Benralizumab (IL-5R mAb)

### Chronic Obstructive Pulmonary Disease (COPD)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III | Moderate to very severe COPD with exacerbation history | N = 2,168 | - Arm 1: 10 mg Q8W SC  
- Arm 2: 30 mg Q4W SC  
- Arm 3: 100 mg Q8W SC  
- Arm 4: Placebo SC  
48-week trial  
Global trial – 23 countries | Rate of COPD exacerbation | FPD: Q3 2014  
Estimated completion: 2018 |
| Terranova | NCT02155660 | | | | |

| Phase III | Moderate to very severe COPD with exacerbation history | N = 1,626 | - Arm 1: 30 mg Q4W SC  
- Arm 2: 100 mg Q8W SC  
- Arm 3: Placebo SC  
48-week trial  
Global trial – 17 countries | Rate of COPD exacerbation | FPD: Q3 2014  
Estimated completion: 2018 |
<p>| Galathea | NCT02138916 | | | | |</p>
<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III STRATOS 1 | Adults with uncontrolled severe asthma | N = 1,140 | Cohort 1:  
• Arm 1: Tralokinumab dose regimen 1, SC  
• Arm 2: Placebo SC  
Cohort 2:  
• Arm 1: Tralokinumab dose regimen 2, SC  
• Arm 2: Placebo SC  
2:1 randomisation in both cohorts  
Global trial – 15 countries | Primary:  
• Asthma exacerbation rate reduction  
Key Secondary:  
• Effect of tralokinumab on measures of pulmonary function (FEV1), asthma symptoms (Asthma Daily Diary), asthma control (ACQ-6) and asthma related QoL (AQLQ (S) +12) | • FPD: Q3 2014  
• LPCD: Q1 2016  
• Estimated completion date: 2017  
• Estimated top-line results: 2017 |
| Phase III STRATOS 2 | Adults with uncontrolled severe asthma | N = 770 | • Arm 1: Tralokinumab SC  
• Arm 2: Placebo SC  
1:1 randomisation  
Global trial – 13 countries including Japan | Primary:  
• Asthma exacerbation rate reduction  
Key Secondary:  
• Effect of tralokinumab on measures of pulmonary function (FEV1), asthma symptoms (Asthma Daily Diary), asthma control (ACQ-6) and asthma related QoL (AQLQ (S) +12) | • FPD: Q1 2015  
• LPCD: H2 2016  
• Estimated completion date: 2017  
• Estimated top-line results: 2017 |
| Phase III TROPOS | Adults with oral corticosteroid dependent asthma | N = 120 | • Arm 1: Tralokinumab SC  
• Arm 2: Placebo SC  
1:1 randomisation  
Global trial – six countries | Primary:  
• % Change in OCS dose  
Key Secondary:  
• Proportion of subjects achieving final daily OCS dose ≤5 mg  
• Proportion of subjects achieving ≥50% reduction in OCS dose | • FPD: Q1 2015  
• LPCD: H2 2016  
• Estimated completion date: 2017  
• Estimated top-line results: 2017 |
| Phase II MESOS | Adults with uncontrolled asthma | N = 80 | • Arm 1: Tralokinumab SC  
• Arm 2: Placebo SC  
1:1 randomisation  
Global trial – three countries | Primary:  
• Change in number of airway submucosal eosinophils  
Secondary:  
• Change in blood eosinophil levels  
• Change in eosinophil cationic protein as a measure of activated eosinophils in blood and sputum | • FPD: Q3 2015  
• LPCD: 2017  
• Estimated completion date: 2017  
• Estimated top-line results: 2017 |
# Tralokinumab (IL-13 mAb)

## Atopic dermatitis

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II</td>
<td>Adults with atopic dermatitis</td>
<td>N = 306</td>
<td>• Arm 1: Tralokinumab dose 45mg SC &lt;br&gt; • Arm 2: Tralokinumab dose 150mg SC &lt;br&gt; • Arm 3: Tralokinumab dose 300mg SC &lt;br&gt; • Arm 4: Placebo SC &lt;br&gt; Global trial – six countries</td>
<td>• Change from baseline in SCORAD at week 12 &lt;br&gt; Key Secondary Endpoints: &lt;br&gt; • Percentage of subjects achieving IGA of 0 or 1 &lt;br&gt; • Change from baseline in EASI &lt;br&gt; • Percentage of subjects achieving EASI50 and SCORAD50 &lt;br&gt; • Change from baseline in pruritis &lt;br&gt; • Safety and tolerability &lt;br&gt; • Tralokinumab serum concentration</td>
<td>• FPD: Q1 2015 &lt;br&gt; • LPCD: Q4 2015 &lt;br&gt; • Completion date: Q1 2016 &lt;br&gt; • Top-line results: Q1 2016</td>
</tr>
</tbody>
</table>
## Anifrolumab (type I IFN receptor mAb)

### Systemic Lupus Erythematosus (SLE)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III NCT02446912</td>
<td>Moderate to severe SLE TULIP SLE 1</td>
<td>N = 450</td>
<td>• Arm 1: 300 mg IV MEDI-546 Q4W for 48 weeks&lt;br&gt;• Arm 2: 150 mg IV MEDI-546 Q4W for 48 weeks&lt;br&gt;• Arm 3: Placebo IV Q4W for 48 weeks</td>
<td>Response in SLE responder index at week 52</td>
<td>• FPD: Q3 2015&lt;br&gt;• LPCD: 2018&lt;br&gt;• Estimated top-line results: 2018</td>
</tr>
<tr>
<td>Phase III NCT02446899</td>
<td>Moderate to severe SLE TULIP SLE 2</td>
<td>N = 360</td>
<td>• Arm 1: 300 mg IV MEDI-546 Q4W for 48 weeks&lt;br&gt;• Arm 2: 150 mg IV MEDI-546 Q4W for 48 weeks</td>
<td>Response in SLE responder index at week 52</td>
<td>• FPD: Q3 2015&lt;br&gt;• LPCD: 2018&lt;br&gt;• Estimated top-line results: 2018</td>
</tr>
<tr>
<td>Phase II NCT01438489</td>
<td>Moderate to severe SLE patients</td>
<td>N = 307 (final)</td>
<td>• Arm 1: 300 mg IV MEDI-546 Q4W for 48 weeks&lt;br&gt;• Arm 2: 1000 mg IV MEDI-546 Q4W for 48 weeks&lt;br&gt;• Arm 3: Placebo IV Q4W for 48 weeks</td>
<td>Response in SLE responder index at 6 months</td>
<td>• FPD: Q1 2012&lt;br&gt;• Top-line results: Q3 2014</td>
</tr>
<tr>
<td>Phase II NCT01753193</td>
<td>Moderate to severe SLE patients</td>
<td>N = 218</td>
<td>• Arm 1: MEDI-546, IV Q4W for 104 weeks</td>
<td>Open-label extension to evaluate long-term safety and tolerability</td>
<td>• FPD: Q1 2013&lt;br&gt;• Estimated top-line results: 2017</td>
</tr>
<tr>
<td>Phase II NCT01559090</td>
<td>Japanese SLE patients</td>
<td>N = 17</td>
<td>Open-label, dose escalation trial:&lt;br&gt;• Arm 1: 100mg IV Q4W for 48 weeks then 300mg IV Q4W for 104 weeks&lt;br&gt;• Arm 2: 300mg IV Q4W for 48 weeks then 300mg IV Q4W for 104 weeks&lt;br&gt;• Arm 3: 1000mg IV Q4W for 48 weeks then1000mg IV Q4W for 104 weeks</td>
<td>Safety, tolerability, PK/PD</td>
<td>• Top-line results: Q1 2015</td>
</tr>
<tr>
<td>Phase I NCT02601625</td>
<td>Healthy volunteers</td>
<td>N= 30</td>
<td>• Arm 1: 300mg SC single dose&lt;br&gt;• Arm 2: 300mg IV single dose&lt;br&gt;• Arm 3: 800 mg SC single dose</td>
<td>Safety, tolerability, PK/PD</td>
<td>• FPD: Q4 2015&lt;br&gt;• LPCD: H1 2016&lt;br&gt;• Estimated top-line results: H2 2016</td>
</tr>
</tbody>
</table>
## Anifrolumab (type I IFN receptor mAb)  
**Lupus Nephritis (LN)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II    | Active Proliferative LN (TULIP-LN1) | N = 150 | Arm 1: 900 mg IV Q4W for 12 weeks then 300 mg IV MEDI-546 Q4W for 36 weeks  
Arm 2: 300 mg IV MEDI-546 Q4W for 48 weeks  
Arm 3: Placebo IV Q4W for 48 weeks | Response in proteinuria at week 52 | FPD: Q4 2015  
LPCD: 2018  
Estimated top-line results: 2018 |
# Acalabrutinib (ACP-196)

## Rheumatoid Arthritis

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoint(s)</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II ACE-RA-001 | Rheumatoid Arthritis | N=70 | • Arm A: Acalabrutinib + methotrexate  
• Arm B: Methotrexate | Disease Activity Score 28-CRP at week 4 | Estimated Completion: 2017 |

- **NCT02367762**
## Roxadustat (HIF-PHI)

### Chronic Kidney Disease (CKD)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III ANDES NCT01750190 | Anaemia in CKD patients not receiving dialysis | N = 600 | - Arm 1: Roxadustat  
- Arm 2: Placebo  
Global trial – 15 countries | Haemoglobin response | • FPD: Q4 2012  
• Estimated completion: 2017  
Sponsored by FibroGen |
| Phase III ALPS NCT01887600 |  | N = 600 | - Arm 1: Roxadustat  
- Arm 2: Placebo  
Global trial – 16 countries | Haemoglobin response | • FPD: Q2 2013  
• Estimated completion: Q2 2016  
Sponsored by Astellas |
| Phase III DOLOMITES NCT02021318 |  | N = 570 | - Arm 1: Roxadustat  
- Arm 2: Darbepoetin alfa  
Global trial – 17 countries | Haemoglobin response | • FPD: Q1 2014  
• Estimated completion: 2017  
Sponsored by Astellas |
| Phase III OLYMPUS NCT02174627 |  | N = 2,600 | - Arm 1: Roxadustat  
- Arm 2: Placebo  
Global trial – 24 countries | MACE | • FPD: Q3 2014  
• Estimated completion: 2017  
Sponsored by AstraZeneca |
| Phase III ROCKIES NCT02174731 | Anaemia in CKD in patients receiving dialysis | N = 1,425 | - Arm 1: Roxadustat  
- Arm 2: Epoetin alfa  
Global trial – 18 countries | MACE | • FPD: Q3 2014  
• Estimated completion: 2017  
Sponsored by AstraZeneca |
| Phase III SIERRAS NCT02273726 |  | N = 600 | - Arm 1: Roxadustat  
- Arm 2: Epoetin alfa  
Global trial – one country | Haemoglobin response | • FPD: Q4 2014  
• Estimated completion: 2017  
Sponsored by FibroGen |
| Phase III PYRENEES NCT02278341 |  | N = 750 | - Arm 1: Roxadustat  
- Arm 2: Erythropoiesis Stimulating Agent  
- Arm 3: Darbepoetin alfa  
Global trial – 19 countries | Haemoglobin response | • FPD: Q4 2014  
• Estimated completion: 2017  
Sponsored by Astellas |
| Phase III HIMALAYAS NCT02052310 | Anaemia in newly initiated dialysis patients | N = 1000 | - Arm 1: Roxadustat  
- Arm 2: Epoetin alfa  
Global trial – 18 countries | Haemoglobin response | • FPD: Q4 2013  
• Estimated completion: 2017  
Sponsored by FibroGen |
Cediranib (VEGF receptor inhibitor)
Ovarian cancer

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III</td>
<td>Patients with platinum-sensitive relapsed ovarian cancer</td>
<td>N = 486</td>
<td>• Arm 1: Placebo</td>
<td>• PFS</td>
<td>• FPD: Q2 2007 • Completed</td>
</tr>
<tr>
<td>ICON 6</td>
<td></td>
<td></td>
<td>• Arm 2: concurrent cediranib</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00532194</td>
<td></td>
<td></td>
<td>• Arm 3: concurrent and maintenance cediranib</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Durvalumab (MEDI4736; PD-L1 mAb)

## Non-small cell lung cancer (NSCLC)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III ADJUVANT | Adjuvant NSCLC patients IB (≥4cm) – IIIA resected NSCLC (incl. EGFR/ALK pos) | N = 1,100 | ▪ Arm 1: MEDI4736 mg/kg IV Q4W x 12 mos  
▪ Arm 2: Placebo  
Global trial | • DFS  
• OS | ▪ FPD: Q1 2015  
▪ Estimated completion: 2020 |
| Phase III PACIFIC | Unresectable Stage III NSCLC patients following platinum-based concurrent chemo-radiation therapy | N = 702 | ▪ Arm 1: MEDI4736 IV Q2W  
▪ Arm 2: placebo  
Global trial | • PFS  
• OS | ▪ FPD: Q2 2014  
▪ LPCD: Q2 2016  
▪ Estimated completion: 2017 |
| Phase II/III Lung Master Protocol | Stage IV squamous NSCLC patients  
Biomarker-targeted 2L therapy | N = 140  
100 Durvalumab treated (4736 substudy only); Umbrella trial with 5 arms based on biomarker expression  
 ▪ Substudy A: MEDI4736 (non-match for other biomarker driven substudies)  
▪ Substudy B: PI3K Inhibitor vs. docetaxel  
▪ Substudy C: CDK4/6 inhibitor vs. docetaxel  
▪ Substudy D: AZD4547 (FGFR inhibitor) vs. docetaxel  
▪ Substudy E: C-MET/HGFR Inhibitor + erlotinib vs. Erlotinib (Substudy is closed)  
Arm 1  
▪ ORR, PDL1 + | ▪ FPD: Q2 2014  
▪ Estimated completion: 2022 |
| Phase II ATLANTIC | Stage IIIB-IV NSCLC patients PD-L1+ve patients  
3L | N = 293 | ▪ Arm 1: MEDI4736 IV Q2W (EGFR/ALK WT)  
▪ Arm 2: MEDI4736 IV Q2W (EGFR/ALK M+)  
▪ Arm 3: MEDI4736 IV Q2W (EGFR/ALK WT) (90% PD-L1 - expression)  
Global trial – 18 countries  
Objective Response Rate  
Secondary endpoints include duration of response, PFS and OS | ▪ FPD: Q1 2014  
▪ LPCD: Q2 2015  
▪ First data: Q4 2015  
▪ Estimated completion: H2 2016 |
| Phase II Sequencing Study | Stage IIIB-IV NSCLC patients  | N = 72 | ▪ Arm 1: Iressa initially then switch to MEDI4736 IVQ2W  
▪ Arm 2: AZD9291 then switch to MEDI4736  
▪ Arm 3: selumetinib + docetaxel then switch to MEDI4736  
▪ Arm 4: tremelimumab then switch to MEDI4736  
Complete Response Rate  
ORR, Disease Control Rate | ▪ FPD: Q3 2014  
▪ LPCD: Q2 2016  
▪ Estimated completion: H2 2016 |
## Durvalumab (MEDI4736; PD-L1 mAb)

Squamous Cell Carcinoma of the Head & Neck (SCCHN) and other solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II</td>
<td></td>
<td></td>
<td>Single-arm: MEDI4736 IV Q2W</td>
<td>ORR</td>
<td>FPD: Q1 2015</td>
</tr>
<tr>
<td>HAWK</td>
<td>SCCHN 2L PD-L1 positive</td>
<td>N = 112</td>
<td></td>
<td></td>
<td>LPCD: Q2 2016</td>
</tr>
<tr>
<td>NCT02207530</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Estimated completion: H2 2016</td>
</tr>
<tr>
<td>Phase I</td>
<td></td>
<td></td>
<td>Dose Escalation: N=36, 3 cohorts receiving Treatment A (mogamulizumab + MEDI4736) and 3 cohorts receiving Treatment B (mogamulizumab + tremelimumab), in parallel</td>
<td>Safety and Tolerability, MTD, ORR, DoR, DCR, PFS, OS</td>
<td>FPD: Q4 2014</td>
</tr>
<tr>
<td>NCT02301130</td>
<td>Solid tumours</td>
<td>N = 108</td>
<td></td>
<td></td>
<td>LPCD: Q4 2015</td>
</tr>
<tr>
<td>Partnered with KHK</td>
<td></td>
<td></td>
<td>Dose Expansion: N=72, Multiple solid tumour types (NSCLC, Head and Neck, Pancreatic), Treatment A or B (12 subjects per treatment per disease type, in parallel)</td>
<td></td>
<td>Estimated completion: H2 2016</td>
</tr>
<tr>
<td>Phase I</td>
<td></td>
<td></td>
<td>Dose Escalation: 3 cohorts at Q2W and 1 cohort at Q3W</td>
<td>Safety</td>
<td>FPD: Q3 2013</td>
</tr>
<tr>
<td>NCT01938612</td>
<td>Solid tumours (all-comers)</td>
<td>N = 176</td>
<td>Dose Expansion: Biliary Tract Cancer, Esophageal Cancer and SCCHN, Q2, and Q4 schedule</td>
<td>Optimal biologic dose</td>
<td>LPCD: Q4 2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose Expansion of combination: Biliary Tract Cancer and Esophageal Cancer, MEDI4736 Q4W 20 mg/kg + tremelimumab Q4W 1 mg/kg</td>
<td></td>
<td>Estimated completion: 2017</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trial conducted in Japan</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

## Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of 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>
<tr>
<td><em>ARCTIC</em></td>
<td>Stage IIIB-IV 3L NSCLC patients who have not be tested positive for EGFR/ALK mutation</td>
<td>N = 480</td>
<td>• Arm 1: MEDI4736 + tremelimumab (PD-L1 –ve patients)</td>
<td>• PFS • OS • Safety</td>
<td>Combination therapy • FPD: Q2 2015 • LPCD: Q2 2016 • Estimated completion: 2017 (PFS, OS)</td>
</tr>
<tr>
<td><em>Mystic</em></td>
<td>NSCLC 1L</td>
<td>N = 780</td>
<td>• Arm 1: MEDI4736</td>
<td>• PFS • OS • Safety</td>
<td>FPD: Q3 2015 • LPCD: Q2 2016 • Estimated completion: 2017</td>
</tr>
<tr>
<td><em>NEPTUNE</em></td>
<td>NSCLC 1L</td>
<td>N = 800</td>
<td>• Arm 1: MEDI4736 + tremelimumab • Arm 2: Standard of care</td>
<td>• OS • Safety</td>
<td>FPD: Q4 2015 • LPCD: 2017 • Estimated completion: 2018</td>
</tr>
<tr>
<td><em>EAGLE</em></td>
<td>SCCHN 2L</td>
<td>N = 720</td>
<td>• Arm 1: MEDI4736 + tremelimumab • Arm 2: MEDI4736 • Arm 3: Standard of care</td>
<td>• OS • PFS • Safety</td>
<td>FPD: Q4 2015 • LPCD: 2017 • Estimated completion: 2018</td>
</tr>
<tr>
<td><em>KESTREL</em></td>
<td>SCCHN 1L</td>
<td>N = 628</td>
<td>• Arm 1: MEDI4736 • Arm 2: MEDI4736 + tremelimumab • Arm 3: Standard of care</td>
<td>• PFS • OS • Safety</td>
<td>FPD: Q4 2015 • LPCD: 2017 • Estimated completion: 2018</td>
</tr>
<tr>
<td><em>DANUBE</em></td>
<td>Bladder 1L cis eligible and ineligible</td>
<td>N = 525</td>
<td>• Arm 1: MEDI4736 + tremelimumab • Arm 2: MEDI4736 • Arm 3: Standard of care</td>
<td>• PFS • OS • Safety</td>
<td>FPD: Q4 2015 • LPCD: 2017 • Estimated completion: 2018</td>
</tr>
</tbody>
</table>
Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

### Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II CONDOR NCT02319044 | SCCHN 2L PD-L1 negative | N = 240 | • Arm 1: MEDI4736  
• Arm 2: Tremelimumab  
• Arm 3: Tremelimumab + MEDI4736 | • ORR  
• Safety | FPD: Q2 2015  
LPDCD: Q2 2016  
Estimated completion: 2017 |
| Phase II ALPS NCT02558894 | Metastatic Pancreatic Ductal Carcinoma 2L | N = 130 | • Arm 1: MEDI4736 + tremelimumab  
• Arm 2: MEDI4736 | • Safety  
• Objective Response rate  
• Pharmacokinetics | FPD: Q4 2015  
LPDCD: 2017  
Estimated completion: 2018 |
| Phase II NCT02527434 | Urothelial Bladder Cancer  
Triple-negative Breast Cancer  
Pancreatic Ductal Adenocarcinoma | N=76 | • Arm 1 Tremelimumab in Urothelial Bladder Cancer  
• Arm 2 TremelimumabTriple-negative Breast Cancer  
• Arm 3 Tremelimumab Pancreatic Ductal-Adenocarcinoma | Safety  
Objective Response rate  
Duration of Response | FPD: Q1 2016  
Estimated completion: 2018 |
| Phase I combination in advanced solid tumours in Japanese patients NCT02141347 | Solid tumours (treme Phase I) | N = 22 | • Tremelimumab + MEDI4736  
• Dose Escalation trial  
• Tremelimumab Q4W/Q12W 3-10mg/kg  
• Tremelimumab Q4W/Q12W X mg/kg + MEDI4736 Q4W X mg/kg | • Safety  
• Optimal biologic dose | FPD: Q2 2014  
LPDCD: Q2 2015  
Estimated completion: H2 2016 |
| Phase I Combination in Advanced Solid Tumours NCT02558214 | Solid tumours | N = 80 | • Arm 1 Ovarian cancer and SCCHN: Durvalumab + tremelimumab + paclitaxel + carboplatin IV infusion  
• Arm 2 SCLC. Durvalumab + tremelimumab + carboplatin + etoposide  
• Arm 3 TNBC: Durvalumab + tremelimumab + gemcitabine + carboplatin  
• Arm 4 TNBC: Durvalumab + tremelimumab + nab-paclitaxel (paclitaxel-albumin) + carboplatin  
• Arm 5 Gastric/gastro-esophageal junction (GEJ): Durvalumab + tremelimumab + oxaliplatin + 5-fluorouracil (5FU) + leucovorin (calcium folinate/folinic acid) | Safety | FPD: Q1 2016  
LPDCD: 2018  
Estimated Completion: 2018 |
Selumetinib (AZD6244) (MEK-inhibitor)

**Solid tumours**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase III**  
SELECT-1  
NCT01933932 | 2L KRASm positive NSCLC | N = 500 |  
• Arm 1: Selumetinib 75mg BID + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle  
• Arm 2: Placebo BID + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle  
Global trial – 26 countries | • PFS  
• OS is a secondary endpoint | • FPD: Q4 2013  
• LPCD: Q1 2016  
• Estimated top-line results: H2 2016 |
| **Phase III**  
ASTRA  
NCT01843062 | Differentiated thyroid cancer | N = 304 |  
• Arm 1: Selumetinib 75mg BID 5 weeks duration + RAI 100mCi  
• Arm 2: Placebo BID 5 weeks duration + RAI 100mCi  
Global trial – eight countries  
*a* Single dose of 100mCi $^{131}$I administered following 4 weeks of selumetinib (or placebo). | • Complete remission (CR) rate at 18 months post-RAI  
• Clinical remission rate at 18 m post RAI (per SoC) | • FPD: Q3 2013  
• LPCD: Q1 2016  
• Estimated top-line results: 2017 |
| **Phase II**  
SELECT-2  
NCT01750281 | 2L KRASm negative NSCLC | N = 225 |  
• Arm 1: Selumetinib 75mg BID + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle  
• Arm 2: Selumetinib 75mg BID + docetaxel 60 mg/m² IV on day 1 of each 21 day cycle  
• Arm 3: Placebo BID + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle  
Global trial – seven countries | • PFS  
• OS is a secondary endpoint | • FPD: Q1 2013  
• LPCD: Q4 2015  
• Estimated top-line results: Q2 2016 |
| **Phase II**  
NCT01362803 (current Ph I) – partnered (NCI) | Pediatric Neurofibromatosis type 1 | N = minimum of 50 symptomatic pts |  
• 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 | • FPD: Q3 2015  
• LPCD: H2 2016  
• Estimated top-line results: 2017 |
| **Phase I**  
NCT02586987 | Advanced solid tumours | N = 40 |  
• Dose escalation trial: Starting dose Selumetinib 50mg bd 1 week on/1 week off - MEDI4736 20mg/kg Q4 – after 7 days of selumetinib dosing.  
Note: No escalation in MEDI4736 dose; Selumetinib escalation with 25 mg bd increment / dose cohort | • Safety and tolerability  
• PK of Selumetinib and MEDI4736 and preliminary anti-tumour activity | • FPD: Q4 2015  
• LPCD: H2 2016  
• Estimated top-line results: 2017 |
# Acalabrutinib (ACP-196)

## Haematological malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoint(s)</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III ACE-CL-006 | Relapsed/refractory chronic lymphocytic leukaemia (CLL), high risk | 500 | • Arm A: Acalabrutinib  
• Arm B: Ibrutinib | PFS  
Secondary endpoints: comparison of incidence of infections, RTTs and atrial fibrillation, OS | • FPD: Q4 2015  
• Estimated Completion: 2018 |
| Early development - IMED | | | | | |
| Phase II ACE-CL-007 | Previously untreated CLL | 510 | • Arm A: Chlorambucil + obinutuzumab  
• Arm B: Acalabrutinib + obinutuzumab  
• Arm C: Acalabrutinib | PFS (Arm A vs Arm B)  
Secondary endpoints: IRC assessed ORR, TTNT, OS (arm A vs Arm B vs. Arm C) | • FPD: Q3 2015  
• Estimated Completion: 2019 |
| Early development - MedImmune | | | | | |
| Phase II ACE-CL-208 | Relapsed/refractory CLL, intolerant to ibrutinib | 80 | Acalabrutinib monotherapy | ORR at 36 cycles | • FPD: Q1 2016  
• Estimated Completion: 2020 |
| Phase II 15-H-0016 | Relapsed/refractory and treatment naïve del17p CLL/small lymphocytic lymphoma (SLL) | 48 | Acalabrutinib monotherapy  
• Arm A: Lymph node biopsy  
• Arm B: Bone marrow biopsy | Safety | • FPD: Q1 2015  
• Estimated Completion: 2017 |
| Phase II ACE-LY-004 | Relapsed/refractory Mantle Cell Lymphoma | 124 | Acalabrutinib monotherapy | ORR | • FPD: Q1 2015  
• LPCD: Q1 2016  
• Enrolment complete  
• Estimated Completion: H2 2016 |
| Phase II ACE-CL-001 | CLL/SLL/Richter's transformation | 286 | Acalabrutinib monotherapy  
Dose escalation and expansion | Safety, PK, PD  
Secondary endpoints: ORR, DOR, and PFS | • FPD: Q1 2014  
• Estimated completion: 2019 |
| Phase II ACE-LY-001 | B-Cell Malignancies | 126 | • Dose escalation and expansion study of the combination of acalabrutinib and ACP-319 (PI3K inhibitor) | Safety  
ORR | • FPD: Q1 2015  
• Estimated completion: 2017 |
| Phase II ACE-LY-005 | Hematological Malignancies | 324 | • Acalabrutinib + pemrolizumab | Safety | • FPD: Q1 2015  
• Estimated completion: 2018 |
# Acalabrutinib (ACP-196)

## Haematological malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoint(s)</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III ACE-WM-001 | Waldenstrom Micoglobulinemia N = 106 | Acalabrutinib monotherapy | ORR | • FPD: Q3 2014  
• LPCD: Q4 2015  
• Enrolment Complete  
• Estimated completion: H2 2016 |
| Phase Ib ACE-LY-002 | Relapsed/refractory de novo ABC Diffuse large B-cell lymphoma N = 21 | Acalabrutinib monotherapy | Safety | • FPD: Q3 2014  
• LPCD: Q2 2016  
• Enrolment Complete  
• Estimated completion: 2017 |
| Phase Ib ACE-LY-106 | Mantle Cell Lymphoma N = 48 | Acalabrutinib in combination with bendamustine and rituximab  
• Arm A: Treatment naive  
• Arm B: Relapsed/refractory | Safety | • FPD estimated: Q2 2016  
• Estimated completion: 2021 |
| Phase Ib ACE-MY-001 | Relapsed/refractory Multiple Myeloma N = 40 |  
• Arm A: Acalabrutinib  
• Arm B: Acalabrutinib + dexamethasone | Safety | • FPD: Q1 2015  
• Estimated completion: 2017 |
| Phase I ACE-LY-003 | Relapsed/refractory Follicular Lymphoma N = 36 |  
• Arm A: Acalabrutinib  
• Arm B: Acalabrutinib + rituximab | Safety | • FPD: Q1 2015  
• Estimated completion: 2018 |
• LPCD: Q3 2015  
• Enrolment complete  
• Estimated completion: 2018 |
| Phase I ACE-CL-003 | CLL/small lymphocytic lymphoma/prolymphocytic leukaemia N = 45 | Acalabrutinib + obinutuzumab  
• Arm A: Relapsed/refractory  
• Arm B: Treatment naive | Safety ORR | • FPD: Q1 2015  
• LPCD: Q1 2016  
• Enrolment complete  
• Estimated completion: 2018 |
# Acalabrutinib (ACP-196)

## Solid Tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Number of 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 squamous cell carcinoma of the head and neck N = 74 | - Arm A: Pembrolizumab  
- Arm B: Acalabrutinib + pembrolizumab | ORR         | FPD: Q2 2015  
Estimated completion: 2017 |
| Phase II ACE-ST-007 NCT02448303 | ≥ 2L advanced or metastatic NSCLC N = 74 | - Arm A: Pembrolizumab  
- Arm B: Acalabrutinib + pembrolizumab | ORR         | FPD: Q2 2015  
Estimated completion: 2017 |
| Phase II ACE-ST-004 NCT02570711 | Recurrent ovarian cancer N = 76 | - Arm A: Acalabrutinib  
- Arm B: Acalabrutinib + pembrolizumab | ORR         | FPD: Q4 2015  
Estimated completion: 2017 |
| Phase II ACE-ST-003 NCT02362048 | 1L metastatic pancreatic cancer N = 120 | - Arm A: Acalabrutinib + Nab-Paclitaxel + Gemcitabine  
- Arm B: Nab-Paclitaxel + Gemcitabine | ORR         | FPD: Q4 2015  
Estimated completion: 2017 |
| Phase II ACE-ST-005 NCT02351739 | ≥ 2L advanced or metastatic pancreatic cancer N = 77 | - Arm A: Acalabrutinib  
- Arm B: Acalabrutinib + pembrolizumab | Safety      | FPD: Q2 2015  
LPID: Q1 2016  
Enrolment complete  
Estimated completion: 2017 |
| Phase II ACE-ST-009 NCT02566867 | Platinum-resistant urothelial bladder cancer N = 78 | - Arm A: Pembrolizumab  
- Arm B: Acalabrutinib + pembrolizumab | ORR         | FPD: Q2 2015  
LPID: Q1 2016  
Enrolment complete  
Estimated Completion 2017 |
| Phase II ACE-ST-008 NCT02566867 | ≥ 2L glioblastoma multiforme N = 72 | Acalabrutinib monotherapy  
- Arm A: 200 mg BID  
- Arm B: 400 mg QD | Safety ORR | FPD: Q1 2016  
Estimated completion: 2018 |
# Moxetumomab pasudotox (CD22 mAb)

## Haematological malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;PLAIT&lt;br&gt;NCT01829711</td>
<td>Adults with relapsed or refractory hairy cell leukemia (HCL)</td>
<td>N = 77</td>
<td>• Multicentre, single-arm, open-label trial3</td>
<td>• Primary: Rate of durable CR: CR maintained for &gt; 180 days&lt;br&gt;• Efficacy: CR rate, ORR, Duration of CR and ORR, time to response (TTR), PFS&lt;br&gt;• Safety and tolerability&lt;br&gt;• PK and immunogenicity</td>
<td>• FPD: Q2 2013&lt;br&gt;• LPCD: H2 2016&lt;br&gt;• Estimated top-line results: 2017</td>
</tr>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;NCT00586924</td>
<td>Adults with relapsed refractory HCL</td>
<td>N = 49</td>
<td>• Open Label dose escalation trial</td>
<td>• MTD and efficacy</td>
<td>• FPD: Q2 2007&lt;br&gt;• LPCD: Q1 2014&lt;br&gt;• Top-line results: Q2 2015 (completed)</td>
</tr>
</tbody>
</table>
## CAZ AVI (BLI/cephalosporin SBI)

### Serious infections

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III  | RECLAIM-1           | Hospitalised patients with complicated intra-abdominal infections | N = 493 | Arm 1: CAZ AVI 2000/500mg plus Metronidazole IV  
Arm 2: Meropenem IV  
Global study – 20 countries | Co primary of:  
(i) clinical response at TOC (MITT)  
(ii) clinical response at TOC (i.e. clinically evaluable) | FPD: Q1 2012  
LPCD: Q2 2014  
Top-line results: Q3 2014 |
|             | NCT01499290        |                     |        |           |        |
| Phase III  | RECLAIM-2           | Hospitalised patients with complicated intra-abdominal infections | N = 577 | Arm 1: CAZ AVI 2000/500mg plus Metronidazole IV  
Arm 2: Meropenem IV  
Global study – 21 countries | Co primary of:  
(i) clinical response at TOC (MITT)  
(ii) clinical response at TOC (i.e. clinically evaluable) | FPD: Q2 2012  
LPCD: Q2 2014  
Top-line results: Q3 2014 |
|             | NCT01500239        |                     |        |           |        |
| Phase III  | RECAPTURE-1         | Hospitalised adults with complicated urinary tract infections | N = 563 | Arm 1: CAZ AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim  
Arm 2: Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim  
Global trial – 26 countries | Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT) | FPD: Q4 2012  
LPCD: Q3 2014  
Top-line results: Q3 2015 |
|             | NCT01595438        |                     |        |           |        |
| Phase III  | RECAPTURE-2         | Hospitalised patients with complicated urinary tract infections | N = 583 | Arm 1: CAZ AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim  
Arm 2: Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim  
Global trial – 25 countries | Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT) | FPD: Q4 2012  
LPCD: Q3 2014  
Top-line results: Q3 2015 |
|             | NCT01599806        |                     |        |           |        |
| Phase III  | REPRISE             | Patients with complicated urinary tract infections and complicated intra-abdominal infections | N = 345 | Arm 1: CAZ AVI 2000/500mg plus Metronidazole IV  
Arm 2: Best available therapy  
Global trial – 30 countries | Patients with clinical cure at the Test of Cure visit in the microbiological intent to treat analysis set | FPD: Q1 2013  
LPCD: Q3 2014  
Top-line results: Q2 2015 |
|             | NCT01644643        |                     |        |           |        |
## CAZ AVI (BLI/cephalosporin SBI)

### Serious Infections

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III</td>
<td>Hospitalised patients with complicated intra-abdominal infections</td>
<td>N = 486</td>
<td>• Arm 1: CAZ AVI 2000/500mg plus Metronidazole IV&lt;br&gt;• Arm 2: Meropenem IV&lt;br&gt;Asia-focused trial – three countries (China, Vietnam &amp; Korea)</td>
<td>• Clinical Cure at the TOC visit in the MITT analysis set</td>
<td>• FPD: Q1 2013&lt;br&gt;• LPCD: Q1 2015&lt;br&gt;• Top-line results: Q3 2015</td>
</tr>
<tr>
<td>RECLAIM-3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01726023</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase III</td>
<td>Hospitalised patients with nosocomial pneumonia infections, including hospital acquired pneumonia (HAP) and ventilator associated pneumonia (VAP)</td>
<td>N = 1,000</td>
<td>• Arm 1: CAZ AVI 2000/500mg IV&lt;br&gt;• Arm 2: Meropenem IV&lt;br&gt;Global trial – 24 countries</td>
<td>• Proportion of patients with clinical cure at the TOC visit in the cMITT and CE analysis sets (co-primary analyses)</td>
<td>• FPD: Q2 2013&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td>REPROVE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01808092</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
AZD3293 (BACE inhibitor)
Alzheimer’s disease

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III</td>
<td>Early Alzheimer’s disease patients</td>
<td>N = 2,202</td>
<td>• Arm 1: AZD3293 20 mg once daily&lt;br&gt;• Arm 2: AZD3293 50 mg once daily&lt;br&gt;• Arm 3: placebo once daily&lt;br&gt;24-month treatment duration&lt;br&gt;Global trial – 14 countries</td>
<td>• Changes in cognitive (ADAS-Cog 13) and functional (ADCS-ADL) scales&lt;br&gt;• Changes in composite scales (CDR-SB)&lt;br&gt;• Changes in biomarkers and imaging assays&lt;br&gt;• Safety and tolerability</td>
<td>• FPD: Q4 2014&lt;br&gt;• LPCD: 2017&lt;br&gt;• Estimated top-line results: 2019</td>
</tr>
<tr>
<td>AMARANTH</td>
<td>NCT02245737</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Cycle management

Late-stage development
Early development - IMED
Early development - MedImmune
Early development - IMED
Verinurad (RDEA3170 - SURI, URAT1 inhibitor)
Gout and hyperuricemia development programme

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase II** | Monotherapy study in subjects with gout | N = 160 | • Arm A: Placebo  
• Arm B: Verinurad 5 mg QD  
• Arm C: Verinurad 10 mg QD  
• Arm D: Verinurad 12.5 mg QD | • Efficacy and Safety at Week 24 | • FPD: Q3 2013  
• LPCD: Q4 2013  
• Study complete |
| NCT01927198 | | | | | |
| **Phase II** | Monotherapy study in Japanese patients with gout or asymptomatic hyperuricemia | N = 200 | • Arm A: Placebo  
• Arm B: Verinurad 5 mg QD  
• Arm C: Verinurad 10 mg QD  
• Arm D: Verinurad 12.5 mg QD  
• Arm E: Open-label Allopurinol 100mg BID | • To compare the efficacy of verinurad monotherapy at Week 16 with placebo and allopurinol | • FPD: Q1 2014  
• LPCD: Q3 2014  
• Study complete |
| NCT02078219 | | | | | |
| **Phase II** | Combination therapy study with febuxostat in subjects with gout | N = 60 | • Arm A: Verinurad 2.5 mg QD  
• Arm B: Verinurad 5.0 mg QD  
• Arm C: Verinurad 10 mg QD  
• Arm D: Verinurad 15 mg QD  
• Arm E: Sequential doses of verinurad 10, 15 and 20 mg QD in combination with 40 mg QD febuxostat | • To assess the PK and PD profiles of verinurad administered with febuxostat | • FPD: Q4 2014  
• LPCD: Q2 2015  
• Estimated completion: Q2 2016 |
| NCT02246673 | | *Arms A-D include combination with 40 mg QD febuxostat for 7 days followed by combination with 80 mg QD febuxostat for 7 days | | | |
| **Phase II** | Combination study with febuxostat for treating gout or asymptomatic hyperuricemia in Japanese patients | N = 92 | • Arm A: Verinurad 2.5 mg QD + 10mg or 20mg QD febuxostat  
• Arm B: Verinurad 5.0 mg QD + 10mg or 20mg QD febuxostat  
• Arm C: Verinurad 5.0 mg QD + 20mg or 40mg QD febuxostat  
• Arm D: Verinurad 10 mg QD + 20mg or 40mg QD febuxostat  
• Arm E: Benzobromarone 50 mg QD | • To assess the PD, PK and safety profiles of verinurad administered with febuxostat | • FPD: Q4 2014  
• LPCD: Q2 2015  
• Estimated completion: Q2 2016 |
| NCT02317861 | | | | | |
## Verinurad (RDEA3170 - SURI, URAT1 inhibitor)

### Gout and hyperuricemia

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II</td>
<td>Combination therapy study with allopurinol in subjects with gout</td>
<td>N = 40</td>
<td>• Arm A: Placebo&lt;br&gt;• Arm B: Verinurad 2.5 mg QD&lt;br&gt;• Arm C: Verinurad 5.0 mg QD&lt;br&gt;• Arm D: Verinurad 7.5 mg QD&lt;br&gt;• Arm E: Verinurad 10 mg QD&lt;br&gt;• Arm F: Verinurad 15 mg QD&lt;br&gt;• Arm G: Verinurad 20 mg QD&lt;br&gt;*All arms include combination with 300 mg QD allopurinol. Placebo group also includes combination with 300 mg BID allopurinol or 600 mg QD allopurinol</td>
<td>• To assess the PK and PD profiles of verinurad administered with allopurinol</td>
<td>• FPD: Q3 2015&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Estimated completion: H2 2016</td>
</tr>
<tr>
<td>NCT02498652</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>Pharmacokinetic and Pharmacodynamic study in healthy adult male subjects</td>
<td>N = 40</td>
<td>Part 1: Single doses of verinurad at 4.5 mg, 6.0 mg, or 12 mg&lt;br&gt;Part 2: Multiple doses of verinurad at 12 mg QD for 7 days&lt;br&gt;Part 3: Food effect study with single doses of verinurad at 6.0 mg</td>
<td>• To assess the PK, PD and food effect profiles of verinurad</td>
<td>• FPD: Q4 2015&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Estimated completion: H2 2016</td>
</tr>
<tr>
<td>NCT02608710</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial phase</td>
<td>Patient population</td>
<td>Number of patients</td>
<td>Design</td>
<td>Endpoints</td>
<td>Status</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------</td>
<td>--------------------</td>
<td>--------</td>
<td>-----------</td>
<td>--------</td>
</tr>
<tr>
<td>Phase II</td>
<td>Patients with mild to moderate asthma</td>
<td>N = 48</td>
<td>A randomised, double blind, multiple dosing (14 days), placebo-controlled, incomplete block crossover, multi centre study to assess efficacy and safety of three dose levels of AZD7594, given once daily by inhalation, in patients with mild to moderate asthma.</td>
<td>• Forced expiratory volume in one second (FEV1)</td>
<td>• FPD: Q3 2015 • Completed</td>
</tr>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>N = 73</td>
<td>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 Volunteers - Suspension inhaled via Spira nebuliser Trial conducted in the UK</td>
<td>• Safety and tolerability</td>
<td>• FPD: Q4 2012 • Completed</td>
</tr>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>N = 24</td>
<td>An open label, partially randomised, four-period study in healthy male subjects to investigate the bioavailability and pharmacokinetics of a single dose of AZD7594 when administered intravenously, orally and inhaled via two different dry powder inhalers (DPI) and a pressurised metered-dose inhaler (pMDI)</td>
<td>• Bioavailability and pharmacokinetics</td>
<td>• FPD: Q1 2016 • Estimated completion: Q2 2016</td>
</tr>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>N = 36</td>
<td>A phase I, randomised, single-blind, placebo-controlled, sequential-group, single-centre study 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</td>
<td>• Safety and tolerability</td>
<td>• FPD: Q1 2016 • Estimated completion: Q2 2016</td>
</tr>
</tbody>
</table>
### AZD7624 (p38 inhibitor)

#### Chronic Obstructive Pulmonary Disease (COPD)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IIa   | COPD               | N = 212            | • Arm 1: AZD7624, 1.0mg  
• Arm 2: placebo  
• Inhaled (nebulised) administration  
Trail conducted in US, EU, South Africa & South America | • Effect on rate of exacerbations and lung function compared to placebo | • FPD: Q4 2014  
• LPCD: Q1 2016  
• Estimated top-line results: Q2 2016 |
| Phase Ib   | Healthy subjects   | N = 30             | • 2-way cross-over RCT  
• Single administration of 1200 μg of AZD7624 or placebo at 0.5 hours prior to lipopolysaccharide (LPS) challenge.  
• Inhaled (nebulised) administration  
Trail conducted in the UK | • Effect on neutrophils in induced sputum after oral inhalation of LPS, compared to placebo | • FSD: Q4 2013  
• Completed |
| Phase I    | Healthy subjects   | N = 48             | SAD  
• Five different dose levels investigated vs placebo  
• Inhaled (nebulised) administration  
Trail conducted in the UK | • Safety and tolerability following inhaled administration with single ascending dose | • FSD: Q1 2013  
• Completed |
| Phase I    | Healthy subjects and COPD | N = 47 | MAD  
• Different dose levels investigated vs placebo in healthy volunteers and patients with COPD  
• Inhaled (nebulised) administration  
Trail conducted in the UK | • Safety and tolerability in healthy subjects and patients with COPD following administration of multiple ascending inhaled doses | • FSD: Q3 2013  
• Completed |
# AZD7986 (DPP1 inhibitor)

## Chronic Obstructive Pulmonary Disease

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>N = 152</td>
<td>Part 1 (SAD)</td>
<td>Safety and tolerability and PK following oral administration with single ascending dose</td>
<td>FPD: Q4 2014</td>
</tr>
<tr>
<td>NCT02303574</td>
<td></td>
<td></td>
<td>• Five different dose levels investigated vs placebo • oral administration</td>
<td>Preliminary assessment of the effect of food on the single dose PK parameters of AZD7986</td>
<td>Completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Part 2 (MAD)</td>
<td>Safety and tolerability &amp; PK in healthy subjects following administration of multiple ascending oral doses</td>
<td>FPD: Q1 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Three different dose levels investigated vs placebo in healthy volunteers • oral administration</td>
<td>• NE activity</td>
<td>LPCD: Q1 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trial conducted in the UK</td>
<td></td>
<td>Estimated completion: Q2 2016</td>
</tr>
</tbody>
</table>
### AZD8871 (MABA2)

**Asthma/Chronic Obstructive Pulmonary Disease (COPD)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase I** | Part 1: Mild Asthmatic  
Part 2: Moderate to severe COPD | N (Part 1) = 16  
N (Part 2) = 40 | Part 1  
SAD trial with 6 planned dose levels - 50 μg, 100 μg, 300 μg, 600 μg, 1200 μg, and up to 1800 μg  
Part 2  
Comprises 5 treatment periods of 36 hours each separated by a washout period of at least 7 to 14 days (one exception per patient of up to 28 days would be acceptable).  
- AZD8871 dose A once daily (double-blind)  
- AZD8871 dose B once daily (double-blind)  
- Indacaterol 150 μg once daily (open-label)  
- Tiotropium 18 μg once daily (open-label)  
- Placebo (double-blind)  
Global trial – one country | Part 1 Endpoints:  
- To assess the safety and tolerability of single doses of AZD8871 administered by inhalation to mild persistent asthmatic male subjects  
- To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8871 in mild persistent asthmatic male subjects  
Part 2 Endpoints:  
- To assess the safety and tolerability of single doses of AZD8871 administered by inhalation to moderate to severe COPD subjects  
- To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8871 in moderate to severe COPD subjects | Part 1  
CTs.gov Identifier: In progress  
FPD: Q4 2015  
LPCD: Q1 2016  
Estimated completion date: 2017 |

Lifecycle management  
Late-stage development  
Early development - IMED  
Early development - MedImmune
# AZD9412 (Inhaled IFN-beta)  
## Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IIa   | Asthma             | N = 220            | • Arm 1: 24 μg (metered dose) AZD9412 once daily for 14 days  
• Arm 2: Placebo once daily for 14 days  
• Inhaled nebulised administration  
Conducted in Argentina, Australia, Colombia, France, Spain, South Korea and UK. | • Proportion of patients with a severe asthma exacerbation during 14 days of treatment | • FPD: Q3 2015  
• LPCD: H2 2016  
• Estimated top-line results: 2017                                      |

**INEXAS**

NCT02491684
## AZD9567 (oSGRM)
### Rheumatoid Arthritis

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of subjects</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy Volunteers</td>
<td>N = 72</td>
<td>SAD trial with 6 dose levels - 2 μg, 10 μg, 40 μg, 100 μg, 200 μg, and up to 400 μg</td>
<td>• A Phase I, Randomised, Single-Blind, Placebo-Controlled trial To Assess The Safety, Tolerability, Pharmacokinetics And Pharmacodynamics Of Single Ascending Oral Doses Of AZD9567 In Healthy subjects</td>
<td>Part</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Global trial – one country</td>
<td></td>
<td>FPD: Q4 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>LPCD: Q2 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Estimated top-line results: H2 2016</td>
</tr>
</tbody>
</table>
AZD4076 (anti-miR 103/107)  
Non-alcoholic Steatohepatitis (NASH)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | Healthy subjects    | N – up to 48      | SAD trial  
- Up to 6 different dose levels investigated vs placebo  
- Sub cutaneous injection | • Safety and tolerability  
• PK parameters | FPD: Q4 2015  
LPCD: H2 2016  
Estimated completion: 2017 |
| NCT02612662 |                     |                   |        |           |        |
## AZD0156 (ATM)

### Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I NCT02588105 | Solid tumours | N = 130 | • Arm 1: AZD0156 + olaparib  
• Arm 2: AZD0156 + irinotecan | • Safety, tolerability, pharmacokinetics and efficacy | Trial conducted in North America, Europe and South Korea. |

  - FPD: Q4 2015
  - Estimated completion: 2018
# AZD1775 (WEE-1)

## Solid tumours, ovarian cancer and Non-Small Cell Lung Cancer

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II    | p53 mutant PSR ovarian cancer | N = 120 | • Arm 1: Carbo/paclitaxel + AZD1775 225mg  
• Arm 2: Carbo/paclitaxel + placebo  
Global trial 10 countries | • PFS  
• Secondary endpoint: OS | • FPD: Q4 2012  
• LPCD: H2 2016  
• Estimated completion: H2 2016 (OS follow up)  
• Note: Data collection for primary outcome measure completed Q4 2014 |
| Phase II    | PR ovarian cancer | N = 70 | • Arm C: Carboplatin + AZD1775  
• Arm D: Pegylated liposomal doxorubicin (PLD) + AZD1775  
Global trial | • Overall Response Rate (ORR)  
• Secondaries: Duration of Response (DOR), PFS, OS, Disease Control Rate, safety and tolerability | • FPD: Q1 2015  
• LPCD: H2 2016  
• Estimated completion: H2 2016 |
| Phase I/II  | Advanced solid tumours | N = 152 | • 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 small cell lung cancer (SCLC)  
Conducted in US, Canada | • Safety and tolerability  
• Secondary endpoints: Overall response rate, Disease Control Rate, Duration or Response, PFS | • FPD: Q3 2015  
• LPCD: 2017  
• Estimated completion: 2017 |
| Phase I     | Advanced solid tumours | N = 18 | • Monotherapy  
Dose escalation trial to determine MTD  
Conducted in US | • Safety and tolerability | • FPD: Q4 2015  
• LPCD: H2 2016  
• Estimated completion: 2017 |
| Phase I     | Advanced solid tumours | N = 36 | • Dose escalation trial (AZD1775 + olaparib)  
Conducted in US | • Safety and tolerability | • FPD: Q3 2015  
• LPCD: Q1 2016  
• Estimated completion: Q2 2016 |
| Phase I     | Advanced solid tumours | N = 18 | • Dose escalation trial (AZD1775 + MEDI4736)  
Conducted in US | • Safety and tolerability | • FPD: Q4 2015  
• LPCD: H2 2016  
• Estimated completion: 2017 |
| Phase I     | Advanced solid tumours | N = 36 | • Dose escalation trial (AZD1775 + carboplatin + paclitaxel:  
AZD1775 + Carbo: AZD1775 + PLD)  
Conducted in Australia, Japan and Republic of Korea | • Safety and tolerability | • FPD: Q1 2015  
• LPCD: H2 2016  
• Estimated completion: 2017 |
## AZD2014 (TORC 1/2)

**Breast and squamous Non-Small Cell Lung Cancer (NSCLC)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase IIb**<br>NCT02403895<br>STORK | Relapsed or refractory squamous NSCLC (at least one prior therapy) | N = 40 | Open label  
Single arm – patient are divided in two groups  
Group A: intensive PK  
Group B: sparse PK  
Dose: intermittent AZD2014 50mg BID (3 days on + 4 days off) + weekly paclitaxel 80 mg/m²  
Multicentre: EU and US trial sites | • Primary: ORR according to RECIST 1.1 by Investigator assessment  
• Secondary: Number of patients experiencing adverse events (AE) and Serious Adverse Events (SAEs) including chemistry, haematology, vital signs and ECG variables | • FPD: Q2 2015  
• LPCD: H2 2016  
• Estimated completion: H2 2016 |
| **Phase II**<br>NCT02216786<br>MANTA | 2L ER+ metastatic breast cancer | N = 316 |  
• Arm 1: Faslodex  
• Arm 2: Faslodex + AZD2014 50mg BD continuous dosing  
• Arm 3: Faslodex + AZD2014 125mg BD two days on, 5 off  
• Arm 4: Faslodex + everolimus  
The trial will be conducted in Europe | • PFS  
• Secondary endpoint: OS | • FPD: Q2 2014  
• LPCD: Q2 2016  
• Estimated completion: 2017 |
| **Phase I**<br>NCT02398747 | Japanese Patients with Advanced Solid Malignancies | N = 18 | Open label  
Monotherapy and combination with paclitaxel cohorts | • Safety and tolerability of AZD2014 monotherapy and in combination with paclitaxel  
PK | • FPD: Q2 2015  
• LPCD: 2017  
• Estimated completion: 2017 |
| **Phase I/II**<br>NCT02599714<br>PASTOR | Postmenopausal women with locally advanced/metastatic estrogen receptor positive (ER+) breast cancer. | N = 225 |  
Part A - Phase I triplet dose finding to determine the maximum tolerated dose (MTD) of the triplet (AZD2014 + palbociclib + fulvestrant)  
Part B - Phase I single arm expansions (AZD2014 + palbociclib + Faslodex)  
Part C - randomised, double-blind, placebo-controlled, stratified, parallel group extension at RP2D for triplet combination (AZD2014 + palbociclib + Faslodex vs matching AZD2014 placebo + palbociclib + Faslodex) | Primary:  
• 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: Best Objective Response Rate (BOR) and Objective Response Rate (ORR) | • FPD: Q1 2016  
• LPCD: 2018  
• Estimated completion: 2019 |
### AZD2811 (AURN)

#### Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | Solid tumours      | N = 72             | • Arm 1: AZD2811 dose escalation  
              • Arm 2: AZD2811 dose expansion  
              AZD2811 + irinotecan  
              Trial conducted in North America | • Safety and tolerability  
              • Pharmacokinetics and efficacy | • FPD: Q4 2015  
              • Estimated completion: 2017 |

Trial conducted in North America.

**Lifecycle management**
- Late-stage development - IMED
- Early development - MedImmune
AZD3759 (EGFRm BBB)
Non-Small Cell Lung Cancer (NSCLC) with lung and/or brain metastases

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I BLOOM NCT02228369 | EGFRm+ NSCLC | N = 47 | • MAD  
• Expansion in LM patients at RP2D with AZD3759  
• Expansion in 12 LM patients at 160mg with AZD9291 including cohort with T790M NSCLC  
Trial conducted four countries | • Safety and tolerability  
• Preliminary anti-tumour activity | • FPD: Q4 2014  
• Estimated completion: LM expansion at RP2D H2 2016  
• AZD9291 LM expansion  
• Estimated primary completion: H2 2016 |
## AZD4547 (FGFR)

### Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II/III Lung Master Protocol  
NCT02154490  
Partnered with NCI and SWOG | Stage IIIB-IV NSCLC patients  
Biomarker-targeted 2L therapy | N = 318 (AZD4547 arm only) | 6-Arm trial based on biomarker expression  
• Arm 1: MEDI4736 Unmatched biomarker  
• Arm 2: AZD4547 (FGFR inhibitor)  
• Arm 3: CDK4/6 inhibitor  
• Arm 5: HGFR Inhibitor  
• Arm 6: CTLA-4 + PD-1 inhibitor | • PFS  
• OS | • FPD: Q4 2014  
• Estimated completion: 2022 (final data collection for primary outcome measure Ph III) |
| Phase II GLOW  
NCT01202591 | Female ER+ breast cancer patients whose disease has progressed following treatment with one prior endocrine therapy | N = 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) | • Part A: MTD of AZD4547 in combination with 25mg exemestane in three schedules of AZD4547  
• Part B Intermediate analysis: Tumour size analysis on 30 FGFR amplified patients  
• Part B Final analysis: PFS | • LPCD: Q2 2014  
• Completed: Q1 2015 |
| Phase II SHINE  
NCT01457846 | Advanced gastro-oesophageal cancer | N = 71 | Arm 1 (FGFR2 polysomy): AZD4547 vs paclitaxel randomised 1:1 (30 to 80 patients)  
Arm 2 (FGFR 2 low gene amplification): AZD4547 vs paclitaxel randomised 3:2 (25 to 80 patients)  
Arm 3 (FGFR2 high gene amplification): AZD4547 vs paclitaxel randomised 3:2 (25 to 80 patients) | • PFS  
• Key Secondary: OS/Tumour size | • Recruitment closed after interim analysis: Q2 2013  
• Completed: Q1 2015 |
| Phase I  
NCT01213160 | Advanced cancer who have failed standard therapy or for whom no standard therapy exists | N = 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. 6 patients)  
Conducted in Japan | • Part A: MTD and Recommended dose for Parts B and C  
• Part B: Safety and tolerance and preliminary anti-tumour activity | • Completed: Q2 2013 |
# AZD4547 (FGFR)

## Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase I** | **AZD4547 (FGFR)** | **NCT00979134** | Advanced cancer who have failed standard therapy or for whom no standard therapy exists | N = 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 | • Part A: MTD and Recommended dose for Parts B and C  
• Part B and C: Safety and tolerability, PK and preliminary anti-tumour activity | Completed: Q1 2014 |
| **Phase I** | **BISCAY** | **NCT02546661** | 2nd+ line Muscle Invasive Metastatic Bladder Cancer in patients who have failed prior therapy | N = 140 | • Multi-drug biomarker-directed trial  
• Monotherapy: AZD4547, durvalumab  
• Combination therapy: AZD4547 + durvalumab, Lynparza + durvalumab, AZD1775 + durvalumab | • Safety and tolerability of the combinations  
• PK and preliminary anti-tumour activity | FPD: Q2 2016  
Estimated completion: 2018 |
# AZD5363 (AKT)

## Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase IIb</strong>&lt;br&gt;NCT01625286</td>
<td>ER+ breast cancer receiving 1st treatment with paclitaxel in the advanced setting</td>
<td>N = 100</td>
<td>• Arm 1: AZD5363 + paclitaxel&lt;br&gt;• Arm 2: AZD5363 placebo + paclitaxel&lt;br&gt;Two strata (50 pts per stratum): PIK3CA mutation positive vs Mutation not detected</td>
<td>• PFS&lt;br&gt;• Response rate (ORR) &amp; OS are secondary endpoints</td>
<td>• FPD: Q1 2014&lt;br&gt;• Estimated primary completion: H2 2016&lt;br&gt;• Estimated completion: 2017</td>
</tr>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;NCT01226316</td>
<td>Breast and gynaecological cancers with PIK pathway mutation</td>
<td></td>
<td>Monotherapy AZD5363 480mg BD 4 days on 3 days off&lt;br&gt;Part C arm 1: Breast with PIK3CA mutation&lt;br&gt;Part C arm 2: Gynaecological with PIK3CA mutation&lt;br&gt;Part D arm 1: Breast with AKT-1 mutation&lt;br&gt;Part D arm 2: Gynaecological with AKT-1 mutation&lt;br&gt;Part D arm 3: Other tumours with AKT-1 mutation&lt;br&gt;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]&lt;br&gt;Part E arm 1: ER+ Breast with AKT-1 mutation (prior Faslodex resistance)&lt;br&gt;Part E arm 2: ER+ Breast with AKT-1 mutation (first exposure to Faslodex)&lt;br&gt;Part F arm 1: ER+ Breast with PTEN mutation (prior Faslodex resistance)&lt;br&gt;Part F arm 2: ER+ Breast with PTEN mutation (first exposure to Faslodex)</td>
<td>• Safety and tolerability&lt;br&gt;• Response Rate (ORR)&lt;br&gt;• Clinical Benefit Rate at 24 wks (CBR24) (Parts E &amp; F only)</td>
<td>• FPD: Q3 2013&lt;br&gt;• Estimated primary completion: H2 17&lt;br&gt;• Part C Arms 1 &amp; 2 completed&lt;br&gt;• Part D Arms 1 &amp; 3 completed&lt;br&gt;• Part D Arm 2 ongoing&lt;br&gt;• Part E Arms 1 &amp; 2 ongoing&lt;br&gt;• CBR24 data for 12 patients per arm estimated Q2/Q3 2017&lt;br&gt;• Part F Arms 1 &amp; 2 ongoing</td>
</tr>
</tbody>
</table>
Savolitinib (AZD6094) (MET)

Papillary renal cell and other cancers

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase II</strong></td>
<td>Papillary renal cell cancer</td>
<td>N = 90</td>
<td>Single arm trial: AZD6094 600mg QD Conducted in UK, Spain, US, Canada</td>
<td>Overall Response Rate</td>
<td>FPD: Q2 2014</td>
</tr>
<tr>
<td>NCT02127710</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01773018</td>
<td>Partnered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase I</strong></td>
<td>Advanced cancer (all-comers)</td>
<td>N = 70</td>
<td>Dose escalation trial Conducted in China</td>
<td>Safety and tolerability</td>
<td>FPD: Q2 2013</td>
</tr>
<tr>
<td>NCT01985555</td>
<td>Partnered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02252913</td>
<td>Partnered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02374645</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## AZD6738 (ATR)

### Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | Solid tumours      | N = 160            | • Arm 1: AZD6738 + carboplatin  
• Arm 2: AZD6738 dose escalation AZD6738 + olaparib  
• Arm 3: AZD6738 + durvalumab  
Trial conducted in North America, Europe and South Korea | • Safety and tolerability  
• Pharmacokinetics and efficacy | • FPD: Q4 2014  
• Estimated completion: 2017 |

**NCT02264678**
# AZD8186 (PI3Kb/d)

## Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I NCT01884285 | Advanced Castrate Resistant Prostate Cancer /sqNSCLC /TNBC and patients with known PTEN-deficient/ mutated or PIK3CM mutated/ amplified advanced solid malignancies. | N = 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 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 1/2 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 antitumour activity (POM)  
• Part C: PK, safety, tolerability and recommended dose/ schedule of AZD8186 in combination with abiraterone. Preliminary assessment of antitumour activity of AZD8186 in combination with abiraterone.  
• Estimated completion: 2018 |

Trial conducted in Canada, US, Spain & UK
## AZD9150 (STAT3)

### Solid and Haematological Cancers

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
## AZD9496 (SERD)

### Breast cancer

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | ER+ Breast Cancer  | N ~ 150            | • 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 | • FPD: Q4 2014  
• Estimated completion: 2017 |

---

- NCT02248090

- **Trial phase:** Phase I
- **Patient population:** ER+ Breast Cancer
- **Number of patients:** N ~ 150
- **Design:** 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.
- **Endpoints:**  
  - Primary Outcome Measures: Safety and tolerability  
  - Secondary Outcome Measures: Single and multiple dose pharmacokinetics of AZD9496  
  - 4β-hydroxycholesterol concentration in blood  
  - Anti-tumour activity
- **Status:**  
  - FPD: Q4 2014  
  - Estimated completion: 2017
## ATM AVI

### Infections

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase I</strong></td>
<td>Healthy volunteers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01689207</td>
<td></td>
<td>N = 12</td>
<td>• Randomised, double-blind, 3-part trial in healthy young and elderly volunteers given Aztreonam and Avibactam alone and in combination</td>
<td>• Safety/tolerability</td>
<td>• FPD Q4 2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N = 56</td>
<td>• Part A: single 1 hour IV infusions</td>
<td>• Pharmacokinetics (secondary)</td>
<td>• LPCD: Q4 2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N = 24</td>
<td>• Part B: single IV infusion on Days 1 and 11 and multiple (every 6 hr) IV infusions on Days 2-10. Various dose regimens of Aztreonam-Avibactam are being tested.</td>
<td>• Completion: Q4 2015</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Total dosed = 94)</td>
<td>• Part C: multiple (every 6 hr) IV infusions Days 1-10 in healthy young and elderly volunteers</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Total enrolled = 124)</td>
<td>Single centre in UK</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# AZD3241 (MPO)

## Multiple System Atrophy (MSA)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II NCT01527695 | Parkinson's disease patients | N = 24 | • Arm 1: AZD3241 600 mg BID for 8 weeks  
Arm 2: Placebo  
Randomisation: 3:1 active to placebo. Three sites in Sweden and Finland | • Microglia activation represented by [11C]PBR28 binding  
Secondary endpoints:  
• PD symptoms measured by UPDRS  
• Plasma MPO activity | • Trial completed |
| Phase II NCT01603069 | Parkinson's disease patients | N = 51 | • Arm 1: AZD3241 300 mg BID for 12 weeks  
Arm 2: AZD3241 600 mg BID for 12 weeks  
Arm 3: Placebo  
Randomisation: 1:1:1 across arms  
13 sites in US | • AEs, labs, vital signs, ECGs  
Secondary endpoints:  
• PD symptoms measured by UPDRS  
• Plasma MPO activity | • Trial completed |
| Phase II NCT02388295 | MSA | N = 54 | • Arm 1: AZD3241 300 mg BID for 12 weeks  
Arm 2: AZD3241 600 mg BID for 12 weeks  
Arm 3: Placebo  
Randomisation: 1:1:1 across arms  
13 sites in US  
Nine sites in Europe | • Microglia activation represented by [11C]PBR28 binding  
Secondary endpoints:  
• AEs, labs, vital signs, ECGs  
• Plasma MPO activity | • FPD: Q2 2015  
• LPCD: H2 2016  
• Estimated top-line results: H2 2016 |
| Phase I NCT00729443 | Healthy subjects | N = 46 | • Active Arms: SAD  
Comparator Arm: placebo  
One site in Sweden | • AEs, labs, vital signs, ECGs  
• PK | • Trial completed |
| Phase I NCT01457807 | Healthy subjects | N = 18 | • Active Arms: MAD  
Comparator Arm: placebo  
One site in UK | • AEs, labs, vital signs, ECGs  
• PK | • Trial completed |
| Phase I NCT00914303 | Healthy subjects | N = 59 | • Active Arms: MAD  
Comparator Arm: placebo  
One site in Sweden | • AEs, labs, vital signs, ECGs  
• PK | • Trial completed |
# AZD8108 (NMDA)

## Phase I clinical development programme

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I NCT02248818 | Healthy volunteers | N = 40 | • Randomised, double-blind, placebo-controlled  
• Part 1 SAD 3 dosage-level cohorts  
• Part 2 MAD 2 dosage-level cohorts (US only trial – one site) | • Safety and tolerability  
Additional endpoints:  
• Pharmacokinetics  
• Pharmacodynamics | FPD: Q4 2014  
LPCD: Q3 2015  
Estimated top-line results: Q2 2016 |
Early development - MedImmune
# Mavrilimumab (GMCSF mAb)

## Rheumatoid arthritis (RA)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II EARTH Explorer 2 NCT01715896 | RA patients who have failed 1 or 2 anti-TNF for efficacy, intolerance or safety, OR inadequate response to DMARDs | N = 138 | • Arm 1: Mavrilimumab SC  
• Arm 2: Golimumab Global trial (ex-US) on MTX background; 17 countries | • ACR 20/50/70 at wk 24  
• DAS28 remission  
• Function (HAQ-DI) | • FPD: Q1 2013  
• LPCD: Q3 2014  
• Top-line results: Q4 2014  
• Completed |
| Phase I NCT02213315 | Healthy Japanese subjects | N = 24 | • Arm 1: Mavrilimumab medium dose SC  
• Arm 2: Mavrilimumab high dose SC  
• Arm 3: Placebo SC UK trial; Japanese subjects | • Pharmacokinetic profile  
• Safety and tolerability | • FPD: Q3 2014  
• LPCD: Q3 2014  
• Top-line results: Q4 2014  
• Completed |
## MEDI5872 (B7RP-1 mAb)

**Systemic Lupus Erythematosus (SLE)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IIa   | Primary Sjögren's syndrome | N = 42 | • Arm 1: MEDI5872 210 mg SC QW for 3 weeks and then Q2W for 9 weeks  
• Arm 2: placebo SC QW for 3 weeks and then Q2W for 9 weeks  
Global trial – five countries | • Safety and tolerability  
• Change in the ESSDAI score from baseline to Day 99 | FPD: Q3 2015  
LPCD: 2017  
Estimated top-line results: 2017 |
| NCT02334306 | Partnered | | | | |

| Phase I | SLE and lupus related inflammatory arthritis | N = 40 | Dose escalation trial:  
• Arm 1: MEDI5872 SC  
• Arm 2: placebo SC  
Global trial – eight countries | Safety and tolerability  
Lupus Arthritis Response Rate | FPD: Q2 2012  
LPCD: Q4 2015  
Estimated top-line results: Q2 2016 |
| NCT01683695 | Partnered | | | | |
# MEDI7836 (IL-13 mAb)

## Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy volunteers</td>
<td>N = 32</td>
<td>• Arm 1: 30 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose&lt;br&gt;• Arm 2: 105 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose&lt;br&gt;• Arm 3: 300 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose&lt;br&gt;• Arm 4: 600 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose</td>
<td>• Safety and tolerability</td>
<td>FPD: Q1 2015&lt;br&gt;LPCD: Q3 2015&lt;br&gt;Top-line results: Q1 2016</td>
</tr>
</tbody>
</table>
# MEDI9929 (TSLP mAb)

## Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II</td>
<td>Adult subjects with inadequately controlled, severe asthma</td>
<td>N = 552</td>
<td>Arm 1: Placebo</td>
<td>Reduction in the annualised asthma exacerbation rate (AER) measured at Week 52</td>
<td>FPD: Q2 2014, LPCD: Q4 2015, Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td>PATHWAY</td>
<td></td>
<td></td>
<td>Arm 2: Low dose MEDI9929 70mg SC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02054130</td>
<td></td>
<td></td>
<td>Arm 3: Medium dose MEDI9929 210mg SC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partnered</td>
<td></td>
<td></td>
<td>Arm 4: High dose MEDI9929 280mg SC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase II</td>
<td>Adult subjects with moderate-to-severe atopic dermatitis</td>
<td>N = 100</td>
<td>Arm 1: Placebo</td>
<td>50% reduction from baseline in the Eczema Area and Severity Index measured at Week 12</td>
<td>FPD: Q2 2015, LPCD: H2 2016, Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td>NCT02523094</td>
<td></td>
<td></td>
<td>Arm 2: Dose of MEDI9929 SC</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# MEDI9314 (IL-4Ra mAb)

## Atopic Dermatitis

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I | Healthy volunteers | N = 44 | • Arm 1: 45mg MEDI9314 (n = 4) or placebo (n = 2) as a single SC dose  
• Arm 2: 150 mg MEDI9314 (n = 4) or placebo (n = 2) as a single SC dose  
• Arm 3: 300 mg MEDI9314 (n = 6) or placebo (n = 2) as a single SC dose  
• Arm 4: 300 mg MEDI9314 (n = 6) or placebo (n = 2) as a single IV dose  
• Arm 5: 300 mg MEDI9314 (n = 6) or placebo (n = 2) as a single SC dose  
(Japanese subjects)  
• Arm 6: 450 mg MEDI9314 (n = 6) or placebo (n = 2) as a single IV dose | • Safety and tolerability  
• Pharmacokinetic profile  
• Incident of ADA antibodies to MEDI9314  
• Change relative to baseline of IL-4-induced STAT6 phosphorylation | • FPD: Q1 2016  
• LPCD: H2 2016  
• Estimated top-line results: H2 2016 |

---

**MEDI9314 (IL-4Ra mAb)**

Lateness management

Late-stage development  
Early development - IMED  
Early development - MedImmune
## Inflammation

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II    | Anti-IL-23 mAb MEDI2070 | Patients with moderate to severe Crohn's disease | N = 121 | • Arm 1: MEDI2070, 700mg IV (210mg SC for OLE)  
  • Arm 2: Placebo, IV  
  Global trial – nine countries | • CDAI response at Week 8 defined by either a CDAI score of < 150 or a CDAI reduction from baseline of at least 100 points | • FPD: Q1 2013  
  • LPCD: Q1 2014  
  • Top-line results: Q2 2014 |
| NCT01714726 | Partnered | NCT02574637 | Partnered | N = 342 | • Arm 1: MEDI2070 High dose  
  • Arm 2: MEDI2070 High-Med dose  
  • Arm 3: MEDI2070 Low-Med dose  
  • Arm 4: MEDI2070 Low dose  
  • Arm 5: Placebo | • The primary endpoint is Crohn's Disease Activity Index (CDAI) clinical remission at Week 8, defined by a CDAI score of <150. | • FPD: Q1 2016  
  • LPCD: 2019  
  • Estimated top-line results: 2018 |
## Other biologics
### Autoimmunity

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III | Inebilizumab Anti-CD19 mAb (MEDI-551) | Adults with Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders (NMO/NMOSD) | N = 212 (estimated) | • Arm 1: MEDI-551 500mg IV  
• Arm 2: placebo IV  
• Open-label extension 300mg Global trial 26 Countries | • Primary: Time to attack  
• Secondary: Attack rate, safety and tolerability | • FPD: Q1 2015  
• LPCD: 2017  
• Estimated top-line results: 2018 |
| Phase I | Anti-CD40L (MEDI4920) | Healthy adults | N = 56 | • Arm 1: 3 mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose  
• Arm 2: 10 mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose  
• Arm 3: 30 mg MEDI4920 (n = 3) or placebo (n = 2) as a single IV dose  
• Arm 4: 100 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose  
• Arm 5: 300 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose  
• Arm 6: 1000 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose  
• Arm 7: 2000 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose | • Safety, tolerability, and pharmacokinetics, anti-drug antibody, inhibition of T-cell dependent antibody response | • FPD: Q2 2014  
• LPCD: Q4 2015  
• Top-line results: Q1 2016 |
# Cardiovascular & metabolic disease

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase IIa</strong></td>
<td>rhLCAT MEDI6012</td>
<td>Adults with stable coronary artery disease (CAD) and low High-density lipoprotein (HDL)</td>
<td>N = 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 &lt;br&gt;• Changes in baseline adjusted post dose HDL-C</td>
<td>• FPD: Q4 2015 &lt;br&gt;• LPCD: Q1 2016 &lt;br&gt;• Top-line results: Q1 2016</td>
</tr>
<tr>
<td>NCT02601560</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase I</strong></td>
<td>rhLCAT MEDI6012</td>
<td>Adults with stable coronary artery disease and low HDL</td>
<td>N = 16</td>
<td>SAD IV</td>
<td>• Safety &lt;br&gt;• Changes in total HDL &lt;br&gt;• Change in Cholestryl Ester</td>
<td>• FPD: Q4 2013 &lt;br&gt;• LPCD: Q4 2014 &lt;br&gt;• Completed: Q4 2014</td>
</tr>
<tr>
<td>NCT01554800</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase I</strong></td>
<td>rh-Factor II MEDI8111</td>
<td>Healthy male subjects</td>
<td>N = 12</td>
<td>SAD IV administration &lt;br&gt;UK trial site</td>
<td>• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, immunogenicity and physical examination</td>
<td>• FPD: Q1 2015 &lt;br&gt;• LPCD: Q4 2015 &lt;br&gt;• Top-line results: Q4 2015 &lt;br&gt;• Complete</td>
</tr>
<tr>
<td>NCT01958645</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase I</strong></td>
<td>GLP-1-Glu MEDI0382</td>
<td>Healthy male subjects</td>
<td>N = 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>• FPD: Q1 2015 &lt;br&gt;• LPCD: Q4 2015 &lt;br&gt;• Top-line results: Q4 2015 &lt;br&gt;• Complete</td>
</tr>
<tr>
<td>NCT02394314</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase I/IIa</strong></td>
<td>MEDI4166</td>
<td>Adults with type-2 diabetes</td>
<td>N ~124</td>
<td>SAD/MAD SC administration</td>
<td>Part A (Ph1) &lt;br&gt;• Safety/tolerability following SC dosing of 4166 &lt;br&gt;Part B (Ph2a) &lt;br&gt;• Characterise the effect of multiple-ascending SC doses on glucose metabolism following an MMTT as measured by glucose AUC &lt;br&gt;• Characterise the effect of multiple-ascending SC doses on LDL-c levels</td>
<td>• FPD: Q4 2015 &lt;br&gt;• LPCD: H2 2016 &lt;br&gt;• Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td>NCT02524782</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Durvalumab (MEDI4736; PD-L1 mAb)

## Immuno-oncology

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase III</td>
<td>PD-L1 (durvalumab, MEDI4736)</td>
<td>Solid tumours</td>
<td>N = 1,038</td>
<td>• Dose Escalation: 5 cohorts at Q2W and 1 cohort at Q3W</td>
<td>• Safety</td>
<td>• FPD: Q3 2012</td>
</tr>
<tr>
<td>NCT01693562</td>
<td></td>
<td></td>
<td></td>
<td>• Dose Expansion: 16 tumour type cohorts at the Q2W MTD defined during dose escalation; one cohort at 20mg Q4W</td>
<td>• Optimal biologic dose</td>
<td>• LPCD: Q4 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Secondary endpoints include PK, immunogenicity and antitumour activity</td>
<td>• Estimated top-line results: 2017</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>PD-L1, azacitidine (MEDI4736, Vidaza)</td>
<td>Myelodysplastic syndrome</td>
<td>N = 41</td>
<td>Dose-escalation and dose-expansion trial</td>
<td>Safety and tolerability of monotherapy and combination</td>
<td>• FPD: Q2 2014</td>
</tr>
<tr>
<td>NCT02117219</td>
<td></td>
<td></td>
<td></td>
<td>• Arm 1: MEDI4736 IV</td>
<td>• Secondary endpoints include duration of response, PFS and OS</td>
<td>• LPCD: Q2 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Global trial – four countries</td>
<td></td>
<td>• Estimated top-line results: 2017</td>
</tr>
</tbody>
</table>
# Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

## Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase Ib/II | Gastric or GEJ adenocarcinoma | N = 174 | • Arm A: durvalumab + tremelimumab 2L  
• Arm B: durvalumab 2L  
• Arm C: tremelimumab 2L  
• Arm D: durvalumab + tremelimumab 3L US and ROW trial centres | • Safety & tolerability, ORR, PFS  
• Secondary endpoints include DCR, OS, DoR, PD-L1 Expression | • FPD: Q2 2015  
• LPCD: 2017  
• Estimated top-line results: 2017 |
| Phase Ib/II | Hepatocellular Carcinoma | N = 129 | • Arm A: durvalumab + tremelimumab  
• Arm B: durvalumab 2L  
• Arm C: tremelimumab 2L | • Safety & tolerability, ORR, PFS  
• Secondary endpoints include DCR, OS, DoR, PD-L1 Expression | • FPD: Q4 2015  
• LPCD: 2018  
• Estimated top-line results: 2018 |
| Phase Ib | Non-small cell lung cancer (Immunotx naïve and Immunotx pretreated patient cohorts) | N = 388 | • Dose Escalation: minimum 5 cohorts exploring various treme Q4W and MEDI4736 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 | • Safety  
• Optimal biologic dose for the combination  
• Secondary endpoints include Antitumour activity, PK and immunogenicity | • FPD: Q4 2013  
• LPCD: H2 2016  
• Estimated top-line results: 2018 |
| Phase I | Solid tumours (Basket trial) | N = 393 | • Dose Exploration: 2 cohorts exploring various Q4W treme and MEDI4736 dose combinations and 2 cohorts exploring various Q2W treme and MEDI4736 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 | • Safety & tolerability  
• Optimal biologic dose for the combination  
• Secondary endpoints include Antitumour activity, PK/PD and immunogenicity | • FPD: Q4 2014  
• LPCD: H2 2016  
• Estimated top-line results: 2018 |
| Phase I | Squamous Cell Carcinoma of the Head & Neck | N = 69 | • Arm A: treatment-naïve, PD-L1+, combo  
• Arm B: treatment-naïve, PD-L1-, combo  
• Arm C: PD-L1/PD-L1 refractory, combo North American trial centres | • Safety & tolerability  
• Secondary endpoints include OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers | • FPD: Q4 2014  
• LPCD: C1 2016  
• Estimated top-line results: 2017 |
# Durvalumab (MEDI4736; PD-L1 mAb) + Iressa (gefitinib)

## Non-small cell lung cancer (NSCLC)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | NSCLC (Escalation phase) EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase) | N = 36 | Escalation phase Standard 3+3 design with 28 days DLT period  
  - Iressa (QD) + MEDI4736 IV  
  Expansion phase  
  - Iressa (QD) + MEDI4736 IV recommended dose  
  Global trial – three countries | • Safety  
  • Optimal biologic dose for the combination  
  • Secondary endpoints include tumour response (CR, PR, SD, PD), Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics | • FPD: Q2 2014  
  • LPCD: Q2 2015  
  • Estimated top-line results: 2017 |

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT02088112</td>
<td>NSCLC (Escalation phase) EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Durvalumab (MEDI4736; PD-L1 mAb) + Tafinlar (dabrafenib)/ Mekinist (trametinib) Melanoma

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of 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>N = 69</td>
<td>Dose Escalation: • Cohort A dabrafenib 150mg BiD/ trametinib 2mg QD/ MEDI4736 IV • Cohort B trametinib 2mg QD/ MEDI4736 IV • Cohort C trametinib 2mg QD/ MEDI4736 IV Dose Expansion: • Each cohort will be expanded at the MTD to enroll a total of 20 subjects per cohort Global trial – two countries</td>
<td>• Safety • Optimal biologic dose for the combination • Secondary endpoints include Objective Response and Disease Control, Duration of Response, Progression-free Survival and OS, Pharmacokinetics and immunogenicity</td>
<td>• FPD: Q1 2014 • LPCD: Q2 2015 • Estimated top-line results: 2017</td>
</tr>
<tr>
<td>NCT02027961</td>
<td>BRAF mutation+ (Cohort A) BRAF wild type (Cohorts B&amp;C)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Global trial – two countries
### MEDI0680 (PD-1 mAb) + durvalumab (MEDI4736)

#### Advanced malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | Advanced malignancies | N = 150            | Dose-escalation phase  
• MEDI4736 IV + MEDI0680 IV  
Dose-expansion phase at selected dose from dose-escalation phase  
• MEDI4736 IV + MEDI0680 IV recommended dose | • 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 | • FPD: Q2 2014  
• LPCD: Q3 2015  
• Estimated top-line results: 2018 |

**NCT02118337**
### MEDI0562 (OX40 mAb)

**MEDI0562 (OX40 mAb) + durvalumab (MEDI4736; PD-L1) or tremelimumumab (CTLA-4 mAb)**

#### Advanced malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>OX40 (MEDI0562)</td>
<td>Advanced malignancies</td>
<td>N = 196</td>
<td>Dose-escalation phase • MEDI0562 IV</td>
<td>• Safety • Determination of MTD • Secondary endpoints include preliminary antitumour activity, pharmacokinetics, biomarker activity, and immunogenicity</td>
<td>FPD: Q1 2015 • LPCD: 2017 • Estimated top-line results: 2017</td>
</tr>
<tr>
<td>NCT02318394</td>
<td></td>
<td></td>
<td></td>
<td>Dose-expansion phase • MEDI0562 IV recommended dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>OX40 (MEDI0562) + durvalumab (MEDI4736; PD-L1)</td>
<td>Advanced malignancies</td>
<td>N = 324</td>
<td>• ARM A: MEDI0562 IV + durvalumab IV • ARM B: MEDI0562 IV + tremelimumab IV</td>
<td>• Safety • Secondary endpoints include preliminary antitumour activity, pharmacokinetics, and immunogenicity</td>
<td>FPD: Q2 2016 • LPCD: 2018</td>
</tr>
</tbody>
</table>
### MEDI6383 (OX40 agonist) + durvalumab (MEDI4736; PD-L1 mAb)

#### Advanced malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I NCT02221960 | Advanced malignancies | N = 212 | Dose-escalation phase  
- MEDI6383 IV  
- MEDI6383 IV + MEDI4736 IV | Safety  
Determination of MTD  
Secondary endpoints include preliminary antitumour activity, pharmacokinetics, Biomarker activity, and immunogenicity | FPD: Q2 2015  
LPCD: H2 2016  
Estimated top-line results: 2018 |
|         |                    |                    | Dose-expansion phase  
- MEDI6383 IV recommended dose  
- MEDI6383 IV + MEDI4736 IV recommended dose | US-only trial |

- **Dose-escalation phase**  
- **MEDI6383 IV**  
- **MEDI6383 IV + MEDI4736 IV**

- **Dose-expansion phase**  
- **MEDI6383 IV recommended dose**  
- **MEDI6383 IV + MEDI4736 IV recommended dose**  
- **US-only trial**
# Inebilizumab (MEDI-551, CD19 mAb)

Haematological malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II    | Adults with relapsed or refractory B-cell diffuse large B-cell lymphoma | N = 170 | - Arm 1: MEDI-551 dose level 1 and ICE/DHAP  
- Arm 2: MEDI-551 dose level 2 and ICE/DHAP  
- Arm 2: Rituxan + ICE/DHAP (Open-label trial) | - ORR, including Complete Response (CR) or Partial Response (PR) | FPD: Q1 2012  
LPCD: Q1 2016  
Estimated top-line results: 2018 |
| Phase I     | Adults with relapsed or refractory B-cell malignancies | N = 18  
Conducted in Japan | - Dose-escalation trial IV | - MTD and efficacy | FPD: Q2 11  
LPCD: Q3 2015  
Top-line results: Q3 2015 |
# MEDI1873 (GITR agonist)

## Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of 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>N = 42</td>
<td>Dose-escalation phase&lt;br&gt;- MEDI1873 IV US trial centres</td>
<td>- Safety&lt;br&gt;- Determination of MTD&lt;br&gt;- Secondary endpoints include PK/PD, preliminary antitumour activity, pharmacokinetics, Pharmacodynamics, and immunogenicity</td>
<td>FPD: Q4 2015&lt;br&gt;LPCD: H2 2016&lt;br&gt;Estimated top-line results: 2019</td>
</tr>
</tbody>
</table>
### MEDI4276 (HER2 ADC mAb)

#### Advanced malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of 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 N = 21-36&lt;br&gt;Dose expansion N = 80</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: Safety &lt;br&gt;• Secondary endpoints include anti-tumour activity, overall response, disease control, PFS, OS and change from baseline tumour size</td>
<td>• FPD: Q4 2015 &lt;br&gt;• LPCD: 2017 &lt;br&gt;• Estimated top-line results: 2018</td>
</tr>
<tr>
<td>NCT02576548</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# MEDI9197 (TLR7/8 agonist)

## Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | Advanced solid tumour malignancies readily accessible for injection | N = 45 | Dose-escalation phase  
  - MEDI9197 IT  
  US trial centres- Ex US under evaluation | • Safety  
  • Determination of MTD  
  • Secondary endpoints include:  
    - Objective response, disease control and duration of response  
    - Intra-tumoural and systemic PK and PD profiles/relationships | FPD: Q4 2015  
  LPCD: 2017  
  Estimated top-line results: 2018 |

**Trial phase:**
- **Phase I**

**Patient population:**
- Advanced solid tumour malignancies readily accessible for injection

**Number of patients:**
- N = 45

**Design:**
- Dose-escalation phase
  - MEDI9197 IT
  - US trial centres- Ex US under evaluation

**Endpoints:**
- Safety
- Determination of MTD
- Secondary endpoints include:
  - Objective response, disease control and duration of response
  - Intra-tumoural and systemic PK and PD profiles/relationships

**Status:**
- FPD: Q4 2015
- LPCD: 2017
- Estimated top-line results: 2018

**Trial ID:**
- NCT02556463

**Patient population details:**
- Advanced solid tumour malignancies readily accessible for injection

**Number of patients:**
- N = 45

**Design details:**
- Dose-escalation phase
  - MEDI9197 IT
  - US trial centres- Ex US under evaluation

**Endpoints details:**
- Safety
- Determination of MTD
- Secondary endpoints include:
  - Objective response, disease control and duration of response
  - Intra-tumoural and systemic PK and PD profiles/relationships

**Status details:**
- FPD: Q4 2015
- LPCD: 2017
- Estimated top-line results: 2018
# MEDI9447 (CD73 mAb) + durvalumab (MEDI4736; PD-L1 mAb)

**Advanced malignancies**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | Advanced malignancies | N = 132 | Dose-escalation phase  
• MEDI9447 IV  
• MEDI9447 IV + durvalumab IV | Safety  
• Determination of MTD  
• Secondary endpoints include PK/PD, preliminary anti-tumour activity, pharmacokinetics, Pharmacodynamics, and immunogenicity | FPD: Q3 2015  
• LPCD: 2018  
• Estimated top-line results: 2018 |
| NCT02503774 |                    | | Dose—expansion phase  
• MEDI9447 IV recommended dose  
• MEDI9447 IV recommended dose + Durvalumab IV  
US and Australian trial centres | | |

Lifecycle management  
Late-stage development  
Early development - IMED  
Early development - MedImmune
<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I/II  | Anti-IGF ligand mAb (MEDI-573) | Patients with HR+ HER2-, 1L, metastatic breast cancer taking aromatase inhibitors | N = 176 | • Arm 1: MEDI-573 IV and Aromatase Inhibitor  
• Arm 2: Aromatase Inhibitor alone  
Open label trial | • PFS  
• Retrospective evaluation of predictive biomarker +ve subgroups | • FPD: Q2 2012  
• LPCD: Q2 2013  
• Estimated top-line results: 2017 |
| Phase I     | Anti-Ang2 mAb (MEDI3617) | Solid tumours and ovarian cancer | N = 25 | • MEDI3617 Dose Escalation | • Safety and tolerability | • FPD: Q4 10  
• LPCD: Q2 2015  
• Top-line results: Q3 2015 (completed) |

| Number       | Design                                                                 | |
|--------------|------------------------------------------------------------------------| |
| N = 16       | • MEDI3617 + bevacizumab dose escalation, administered Q3W, IV (US only) | |
| N = 13       | • MEDI3617 + paclitaxel dose escalation, IV (US only)                   | |
| N = 7        | • MEDI3617 + carboplatin + paclitaxel dose escalation, IV (US only)     | |
| N = 27       | • MEDI3617 + bevacizumab dose escalation, administered Q2W, IV (US only) | |
| N = 17       | • MEDI3617 single-agent expansion in ovarian cancer patients, IV (US only) | |
| N = 15       | • MEDI3617 + bevacizumab dose expansion in recurrent malignant glioma  
• US-only trial centres | |
## Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase I     | Anti-CEA BiTE mAb (MEDI-565) | Adults with gastrointestinal (GI) adenocarcinoma with no available standard or curative treatments. Refractory pancreatic, colorectal and gastro-esophageal cancers | N = 51 max N = 60 max, 20 in each cohort | Dose-escalation (3+3), IV Dose expansion trial, IV | MTD and safety profile | FPD: Q1 11  
LPCD Q3 2014  
Top-line results: Q1 2015 completed |
| Phase I     | Anti-DLL4 mAb (MEDI0639) | Adults with advanced solid tumours including SCLC | N = up to 28 | Dose-escalation trial (3+3), IV | MTD and safety profile | FPD: Q2 2012  
LPCD: Q2 2015  
Estimated top-line results: H2 2016 |
## Vaccine biologics

### Influenza vaccines

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III   | MEDI3250 | Children 2 to 6 years of age | N = 100 | • Open-label  
• Route of administration: intranasal | • Safety and tolerability | FPD: Q4 2014  
LPCD: Q1 2015  
Top-line results: Q1 2015 (completed) |
| NCT02269488 | FluMist | | | | | |
| Phase III   | MEDI3250 | Children 7 through 18 years of age | N = 1,008 | • Randomised, double-blind placebo-controlled  
• Route of administration: intranasal | • Efficacy assessed by incidence of laboratory-confirmed influenza-like illness in the two treatment arms  
• Safety and tolerability | FPD: Q4 2014  
LPCD: Q4 2014  
Top-line results: Q2 2015 (completed) |
| NCT02269475 | FluMist Quadrivalent | | | | | |
### Other biologics

#### Infections

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase II</td>
<td>Anti-Staph AT (MEDI4893)</td>
<td>Intubated ICU</td>
<td>N = 462</td>
<td>Placebo-controlled, single-dose, dose-ranging</td>
<td>Efficacy and Safety</td>
<td>FPD: Q4 2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Route of administration: intravenous</td>
<td></td>
<td>LPCD: 2017</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• FPD: Q4 2014</td>
<td></td>
<td>Estimated top-line results: 2017</td>
</tr>
<tr>
<td>Phase Ib</td>
<td>RSV sF+GLA-SE (MEDI7510)</td>
<td>Adults ≥ 60 yrs</td>
<td>N = 1,901</td>
<td>Randomised, Double-blind trial</td>
<td>Efficacy</td>
<td>FPD: Q3 2015</td>
</tr>
<tr>
<td>Phase Ib</td>
<td>RSV sF+GLA-SE (MEDI7510)</td>
<td>Adults ≥ 60 yrs</td>
<td>N = 264</td>
<td>Double blind, randomised, placebo and active controlled cohort escalation trial</td>
<td>Safety and tolerability</td>
<td>LPCD: H2 2016</td>
</tr>
<tr>
<td>Phase Ib</td>
<td>RSV sF+GLA-SE (MEDI7510)</td>
<td>Adults ≥ 60 yrs</td>
<td>N = 144</td>
<td>Double blind, randomised, placebo and active controlled cohort escalation trial</td>
<td>Humoral and cell-mediated immune responses</td>
<td>Top-line results: Q1 2016</td>
</tr>
<tr>
<td>Phase Ib/IIa</td>
<td>Anti-RSV mAb-YTE (MEDI8897)</td>
<td>32-35 WK GA infants</td>
<td>N = 89</td>
<td>Randomised, Double-blind, Placebo-controlled, Dose-escalation trial</td>
<td>Evaluate Safety, Tolerability, PK and ADA</td>
<td>FPD: Q1 2015</td>
</tr>
<tr>
<td>Phase Ib/IIa</td>
<td>Anti-RSV mAb-YTE (MEDI8897)</td>
<td>Healthy adults</td>
<td>N = 136</td>
<td>Randomised, Double-blind, Placebo-controlled, Dose-escalation trial</td>
<td>Evaluate Safety, Tolerability, PK and ADA</td>
<td>LPCD: Q3 2015</td>
</tr>
<tr>
<td>Phase Ib/IIa</td>
<td>Anti-influenza A mAb (MEDI8852)</td>
<td>Adults</td>
<td>N = 160</td>
<td>Randomised, Partial Double-blind, Single Dose, Active-controlled, Dose Flanging trial</td>
<td>Evaluate Safety in Adults with Acute, Uncomplicated Influenza</td>
<td>FPD: Q4 2015</td>
</tr>
<tr>
<td>Phase II</td>
<td>Anti-Influenza A mAb (MEDI3902)</td>
<td>Intubated ICU</td>
<td>N = 429</td>
<td>Placebo-controlled, single-dose, dose-ranging</td>
<td>Efficacy and Safety</td>
<td>FPD: Q3 2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Route of administration: intravenous/</td>
<td></td>
<td>LPCD: Q1 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• FPD: H1 2016</td>
<td></td>
<td>Top-line results: Q2 2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Estimated top-line results: 2018</td>
<td></td>
<td>Complete</td>
</tr>
</tbody>
</table>

**Note:** FPD = First Patient Dosed; LPCD = Last Patient Completed Double; FHE = First Healthy Volunteer Enrolled; IV = Intravenous; IM = Intramuscular; ADA = Anti-Drug Antibodies.
## MEDI1814 (amyloid beta mAb)

### Alzheimer’s disease

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of 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>N = 121</td>
<td>• SAD &amp; MAD</td>
<td>• Safety, tolerability</td>
<td>FPD: Q2 2014</td>
</tr>
<tr>
<td>NCT02036645</td>
<td></td>
<td></td>
<td>• Up to 10 iv cohorts are planned vs placebo</td>
<td></td>
<td>LPCD: H2 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 2 SC cohorts are planned vs placebo</td>
<td></td>
<td>Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>US only</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>