Clinical trials appendix
Q2 2016 update
The following information about AstraZeneca clinical trials in Phases I-IV has been created with selected information from https://clinicaltrials.gov/ to facilitate understanding of key aspects of ongoing clinical programmes and is correct to the best of the Company’s knowledge as of 30 June 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 (https://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>Life-Cycle 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>
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<tr>
<td>SAD</td>
<td>Single Ascending Dose trial</td>
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<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>
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### Movement since Q1 2016 update

<table>
<thead>
<tr>
<th>New to Phase I</th>
<th>New to Phase II</th>
<th>New to Pivotal Study</th>
<th>New to Registration</th>
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<tr>
<td><strong>NMEs</strong></td>
<td><strong>NMEs</strong></td>
<td><strong>NMEs</strong></td>
<td><strong>NMEs</strong></td>
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<tr>
<td>AZD4635</td>
<td>AZT AVI*</td>
<td>ATM AVI*</td>
<td>ATM AVI*</td>
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<tr>
<td>A1aR inhibitor solid tumours</td>
<td>monobactam/beta lactamase inhibitor</td>
<td>TATTON</td>
<td>TATTON</td>
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<tr>
<td>MEDI0562*+tremelimunab</td>
<td>Tagriso combo*</td>
<td>EGFR+PD-L1/MET NSCLC</td>
<td>EGFR+PD-L1/MET NSCLC</td>
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<tr>
<td>hOX40 agonist+CTLA-4 solid tumours</td>
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<tr>
<td>MEDI0562*+durvalumab*</td>
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<tr>
<td>hOX40 agonist+PD-L1 solid tumours</td>
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<table>
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<tr>
<th>Removed from Phase I</th>
<th>Removed from Phase II</th>
<th>Removed from Phase III</th>
<th>Removed from Registration</th>
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<td><strong>NMEs</strong></td>
<td><strong>NMEs</strong></td>
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<td>MED10639*</td>
<td>MEDI-550*</td>
<td>MEDI-550*</td>
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<td>DLL-4 mAb solid tumours</td>
<td>pandemic influenza virus vaccine</td>
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<tr>
<td>durvalumab*MEDI6383</td>
<td>Zavicetta* (CAZ AVI)*</td>
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<td>PD-L1 mAb+OX40 agonist solid tumours</td>
<td>BLI/cephalosporin SBI/cIAI/cUTI</td>
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<tr>
<td>MEDI6383*</td>
<td>saxagliptin/dapagliflozin FDC*</td>
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<td>OX40 agonist solid tumours</td>
<td>DPP-4/SGLT2 inhibitors type-2 diabetes</td>
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<td>MED17536</td>
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<tr>
<td>IL-13 mAb YTE asthma</td>
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</table>

*Partnered and/or in collaboration

1 MAA approval Q2 2016 (MEDI-550 does not count toward late-stage NME totals) 2 MAA approval Q2 2016 3 MAA approval 19 July 2016 4 Farxiga in the US; Forxiga in rest of world
Q2 2016 New Molecular Entity (NME) Pipeline

<table>
<thead>
<tr>
<th>Phase I</th>
<th>32 New Molecular Entities</th>
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<tbody>
<tr>
<td>Small molecule</td>
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<tr>
<td>AZD1150</td>
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<td>AZD3965</td>
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<table>
<thead>
<tr>
<th>Phase II</th>
<th>26 New Molecular Entities</th>
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<td>Small molecule</td>
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<td>BAD3610</td>
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<table>
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<tr>
<th>Phase III</th>
<th>10 New Molecular Entities</th>
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<tr>
<td>Small molecule</td>
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<table>
<thead>
<tr>
<th>Applications Under Review</th>
<th>3 New Molecular Entities</th>
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<td>MED0710</td>
</tr>
<tr>
<td>BAD3610</td>
<td>MED0710</td>
</tr>
</tbody>
</table>

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

# Partnered and/or in collaboration; ¶ Registrational P2/3 study
Q2 2016 Lifecycle Management (LCM) Pipeline

<table>
<thead>
<tr>
<th>Phase</th>
<th>Small molecule</th>
<th>Large molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>11 Projects</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>4 Projects</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>8 Projects</td>
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</tr>
</tbody>
</table>

**Pipeline**

- Includes significant LCM projects and parallel indications for assets in P3 or beyond. Excludes LCM projects already launched in a major market
- # Partnered and/or in collaboration; ¶ Registrational P2/3 study

**Applications Under Review**

<table>
<thead>
<tr>
<th>Applications Under Review</th>
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</thead>
<tbody>
<tr>
<td>1 Project</td>
</tr>
<tr>
<td>Small molecule</td>
</tr>
</tbody>
</table>

**Oncology Combinations**

- A271728/4488-16
- P1-1579/1587-16
- A271728/1574-16
- P1-1579/1587-16
- A271728/4488-16
- P1-1579/1587-16

- A271728/4488-16
- P1-1579/1587-16
- A271728/1574-16
- P1-1579/1587-16
- A271728/4488-16
- P1-1579/1587-16

**Applications Under Review**

- Small molecule: Phase 1
- Large molecule: Phase 1

**Infection, neuroscience, gastrointestinal**

**Respiratory and autoimmunity**

**Cardiovascular and metabolic disease**

**Oncology**

**Infection, neuroscience, gastrointestinal**

**Respiratory and autoimmunity**

**Cardiovascular and metabolic disease**

**Oncology**
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 200μg bid  
• Arm 2: Pulmicort 200 μg Turbuhaler bid + terbutaline 0.4mg Turbuhaler 'as needed'  
• Arm 3: terbutaline Turbuhaler 0.4mg 'as needed' + placebo Pulmicort 200μg 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 160/4.5μg 'as needed' + Placebo Pulmicort Turbuhaler 200μg bid  
• Arm 2: Pulmicort 200μg Turbuhaler bid + terbutaline 0.4mg Turbuhaler 'as needed'  
Global trial – 25 countries | • 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>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IV | Patients with COPD | N = 224 | • Arm 1: Aclidinium bromide 400μg  
• Arm 2: Placebo to aclidinium bromide 400μg  
Global Trial– 5 countries | • Change from baseline in Overall E-RS Total score (i.e. score over the whole 8 weeks study 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  
• Topline results released: Q1 2016  
• Estimated Completion: H2 2016 |
| Phase IV | Patients with moderate to very severe COPD | N = 4,000 | • Arm 1: Aclidinium bromide 400μg  
• Arm 2: Placebo to aclidinium bromide 400μg  
Global Trial– 2 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 hospitalizations due to COPD exacerbation per patient per year during the first year of treatment  
• Time to first Major Adverse Cardiovascular Event (MACE) or other serious cardiovascular events of interest. Up to 36 months | • FPD: Q3 2013  
• LPCD: H2 2016  
• Estimated Topline Results: 2018  
• Estimated Completion: 2018 |
| Phase IV | Patients with stable moderate and severe COPD | N = 30 | • Arm 1: aclidinium bromide 400μg  
• Arm 2: Placebo to Aclidinium bromide 400μg  
Local Trial– 1 country | • Change from baseline in normalized forced expiratory volume in one second (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 study drug administration (for completed patients) or premature discontinuation visit (when applicable) to record adverse events | • FPD: Q2 2014  
• LPCD: Q1 2015  
• Clinically Completed  
• Topline results released: Q4 2015  
• Estimated Completion: 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>
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</thead>
<tbody>
<tr>
<td>Phase IIb</td>
<td>ACHIEVE</td>
<td>N = 120</td>
<td></td>
<td>• Arm 1: Aclidinium/formoterol FDC 400/12μg&lt;br&gt;• Arm 2: Placebo to aclidinium/formoterol FDC 400/12μg&lt;br&gt;Global Trial– 1 Country&lt;br&gt;• Change from baseline in normalized FEV1 area under the curve (AUC) over the 12 h period immediately after morning study drug administration, AUC0-12/12h at Day 7 on treatment&lt;br&gt;• Change from baseline in FEV1 AUC0-6/6h at Day 1 and Day 7 on treatment.&lt;br&gt;• Change from baseline in morning predose FEV1 at Day 7 on treatment&lt;br&gt;• FPD: H2 2016&lt;br&gt;• LPCD: H1 2017&lt;br&gt;• Estimated Topline Results: H2 2017&lt;br&gt;• Estimated Completion: H2 2017</td>
<td></td>
</tr>
<tr>
<td>Phase III</td>
<td>AMPLIFY</td>
<td>N = 1,500</td>
<td>• Arm 1: Aclidinium bromide 400μg/Formoterol Fumarate 12μg&lt;br&gt;• Arm 2: Aclidinium bromide 400μg&lt;br&gt;• Arm 3: Formoterol fumarate 12μg&lt;br&gt;• Arm 4: Tiotropium 18μg&lt;br&gt;Global Trial– 13 Countries&lt;br&gt;• Change from baseline in 1-hour morning post-dose dose FEV1 of AB/FF 400/12μg compared to AB 400 μg at week 24&lt;br&gt;• Change from baseline in morning predose (trough) FEV1 of AB/FF 400/12μg compared to FF 12μg at week 24&lt;br&gt;• Change from baseline in morning predose (trough) FEV1 at week 24&lt;br&gt;• comparing AB 400μg versus TIO 18 μg</td>
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<td></td>
</tr>
<tr>
<td>Phase IV</td>
<td>ACTIVATE</td>
<td>N = 268</td>
<td>• Arm 1: Aclidinium/formoterol FDC 400/12μg&lt;br&gt;• Arm 2: Placebo to aclidinium/formoterol FDC 400/12μg&lt;br&gt;Global Trial– 5 Countries&lt;br&gt;• Change from baseline in trough Functional Residual capacity (FRC) after 4 weeks of treatment&lt;br&gt;• 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&lt;br&gt;• Percentage of inactive patients (&lt;6000 steps per day) after 8 weeks on treatment&lt;br&gt;• FPD: Q2 2015&lt;br&gt;• LPCD: Q2 2016&lt;br&gt;Estimated Topline Results: H2 2016&lt;br&gt;Estimated Completion: H2 2016</td>
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</table>

CO-FUNDED: Menarini
**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>
</table>
| Phase IV RESPOND NCT01443845 | COPD | N = 2,354 | 52W, randomised, DB with Daliresp 500µg OD vs placebo, in COPD on top of ICS/LABA | Rate of moderate or severe COPD exacerbations per subject per year | Completed: Q1 2016  
Estimated results: H2 2016 |
| Phase IV OPTIMIZE NCT02165826 | COPD | N = 1,323 | 12W, randomised, DB to evaluate tolerability and PK of Daliresp 500µg OD with an up-titration regimen during the first 4Ws, including an open label down-titration evaluating tolerability and PK of 250µg Roflumilast OD in subjects not tolerating 500µg OD | Percentage of participants prematurely discontinuing study treatment for any reason during the main period | Completed: Q3 2015  
Estimated results: H2 2016 |
| Phase IIIb ROBERT NCT01509677 | COPD | N = 158 | 16W, randomised, placebo-controlled, DB, parallel-group trial to assess the anti-inflammatory effects of Roflumilast in COPD | Number of inflammatory cells CD8+ in bronchial biopsy tissue specimen (sub-mucosa) measured at randomisation and at the end of the intervention period | Completed: Q1 2016  
Estimated results: H2 2016 |
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>NCT01808131</td>
<td>Gout previously enrolled in studies Phase III RDEA594-301 &amp; -302 (CLEAR 1 &amp; 2) trials</td>
<td>N = 717</td>
<td>• Zurampic 200 or 400mg QD All patients: SOC allopurinol QD Protocol amended Oct 2015: All patients to receive Zurampic treatment dose of 200mg QD in combination with their allopurinol</td>
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<td>Phase III</td>
<td>RDEA594-307 CRYSTAL Extension</td>
<td>NCT01808144</td>
<td>Gout previously enrolled in Phase III RDEA594-304 (CRYSTAL) trial</td>
<td>N = 196</td>
<td>• Zurampic 200 or 400mg QD All patients: febuxostat 80mg QD Protocol amended Oct 2015: All patients to receive Zurampic treatment dose of 200mg QD in combination with their febuxostat</td>
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<td>Phase II</td>
<td>RDEA594-203 Open-label Extension</td>
<td>NCT01001338</td>
<td>Gout previously enrolled in Phase II RDEA594-203 trial</td>
<td>N = 87</td>
<td>• Zurampic 200, 400, or 600mg QD All patients: SOC allopurinol QD Protocol amended Oct 2015: All patients to receive Zurampic treatment dose of 200mg QD in combination with their allopurinol</td>
</tr>
</tbody>
</table>

Lesinurad/allopurinol FDC (SURI, URAT1 inhibitor/XOI inhibitor)

<table>
<thead>
<tr>
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</thead>
</table>
## Bevespi Aerosphere (LABA/LAMA)
### Chronic Obstructive Pulmonary Disease (COPD)

<table>
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<tr>
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</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) 14.4/9.6μg BiD  
- Arm 2: GP MDI (PT001) 14.4μg BiD  
- Arm 3: FF MDI (PT005) 9.6μg BiD  
- Arm 4: Open-label Icotropium bromide inhalation powder 18μg 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 = 1,615 | Treatment (24-week Treatment Period)  
- Arm 1: GFF MDI (Bevespi Aerosphere) 14.4/9.6μg BiD  
- Arm 2: GP MDI (PT001) 14.4μg BiD  
- Arm 3: FF MDI (PT005) 9.6μg 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 = 893 | Treatment (28-week Treatment Period)  
- Arm 1: GFF MDI (Bevespi Aerosphere) 14.4/9.6μg BiD  
- Arm 2: GP MDI (PT001) 14.4μg BiD  
- Arm 3: FF MDI (PT005) 9.6μg BiD  
- Arm 4: Open-label Icotropium 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>
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</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) • GFF 14.4/9.6µg • Placebo MDI BID Open-label and multiple-centre Estimated time from FSFV to DBL is approximately 11 weeks, US</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 • LPCD: Q4 2014 • Top-line results: Q1 2015*</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) • GFF MDI 14.4/9.6µg BID • Placebo MDI BID Randomised, 2-period, 2-treatment Double-blind, Multi-centre and Cross-over Estimated time from FSFV to DBL is approximately four months, US</td>
<td>• FEV1 AUC0-24 on Day 29</td>
<td>• FPD: Q1 2015 • LPCD: Q1 2015 • Top-line results: Q3 2015*</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) • GFF MDI 14.4/9.6µg BID • Placebo • Spiriva Respimat 5 µg QD (open-label) Randomised and 3-way cross-over Estimated time from FSFV to DBL is approximately six months, US</td>
<td>• FEV1 AUC0-24 on Day 29</td>
<td>• FPD: Q1 2015 • LPCD: Q2 2015 • Top-line results: Q3 2015*</td>
</tr>
<tr>
<td>Phase III (Spacer trial) NCT02454959</td>
<td>Moderate to severe COPD</td>
<td>N = 80</td>
<td>Treatments (2 week treatment Period) • GFF MDI 14.4/9.6µg with a spacer • GFF MDI 14.4/9.6µg without a spacer Randomised, 7-day, cross-over in subjects with moderate to severe COPD Estimated time from FSFV to DBL is approximately nine months, US</td>
<td>• Change from morning pre-dose trough FEV1: GFF 14.4/9.6µg with Aerochamber Plus VHC relative to GFF 14.4µg w/o Aerochamber Plus VHC on Day 8 • PK parameters at all doses will include Cmax, AUC0-12, AUC0-24, tmax. Other PD/PK parameters may be calculated, as appropriate</td>
<td>• FPD: Q2 2015 • LPCD: Q1 2016 • Top-line results: Q2 2016*</td>
</tr>
</tbody>
</table>

* Clinically completed
# Bevespi Aerosphere (PT003, LABA/LAMA)

## Chronic Obstructive Pulmonary Disease (COPD)

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<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**<br>(Asia Pacific trial)<br>NCT02343458 | Moderate to very severe COPD | N = 1,614 | Treatments (24-week Treatment Period)  
• GFF 14.4/9.6µg (N=514)  
• GP 14.4µg (N=440)  
• FF 9.6µg (N=440)  
• Placebo (N=220)  
• US/China: Trough FEV1 at week 24 of treatment  
• EU/Hybrid: Co-primary= Trough FEV1 over week 24 of treatment and TDI score over 24 weeks  
Randomised, Double-Blind, Chronic-Dosing , Placebo-Controlled, Parallel-Group and Multi-Centre  
Estimated time from FSFV to DBL is approximately 20 months US, UK, Germany, Costa Rica, Hungary, Poland, Russia, South Korea, Taiwan, China, Japan | • 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 Japan approach, the primary endpoint will be the change from baseline in morning pre-dose trough FEV1 over weeks 12 to 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  
• TDI score (co-primary endpoint for EU and Hybrid) [Time Frame: Over 24 weeks] | • FPD: Q2 2015  
• LPCD: H2 2016  
• Estimated top-line results: H2 2017 |
| **Phase IIb**<br>(CV trial)<br>NCT02685293 | Moderate to severe COPD | N = 40 | Treatments (5-week Treatment Period)  
• GFF MDI (PT003) 14.4/9.6 µg ex-actuator  
• Placebo MDI  
Randomised, 2-period, Double-Blind, 2-treatment, Chronic-Dosing (7 Days), Crossover trial  
Estimated time from FSFV to DB is approximately eight months, US | • Right Ventricular End Diastolic Volume Index (RVEDVi) measured at 2-hours post-dose on Day 8 | • FPD: H2 2016  
• LPCD: H1 2017  
• Estimated top-line results: H1 2017 |
# Brilinta (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 (primary)</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III PEGASUS  
NCT01225562 | Patients with prior MI | N = 21,000 | • Arm 1: Brilinta 90mg BID  
• Arm 2: Brilinta 80mg 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: Q2 2013  
• Completion date: Q4 2014 |
| Phase III EUCLID  
NCT01732822 | Patients with PAD | N = 13,500 | • Arm 1: Brilinta 90mg BID  
• Arm 2: Clopidogrel 75mg QD  
Global trial – 28 countries | • Composite of CV death, non-fatal MI and ischemic stroke | • FPD: Q4 2012  
• LPCD: Q1 2014  
• Estimated top-line results: H2 2016 |
| Phase III THEMIS  
NCT01991795 | Patients with type-2 diabetes and coronary artery disease without a previous history of MI or stroke | N = 19,000 | • Arm 1: Brilinta 60mg 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: Q2 2016  
• Estimated top-line results: 2018 |
| Phase III (BE)  
NCT02436577 | Japanese healthy volunteers | N = 36 | Single dose, Cross-Over  
• Arm 1: Brilinta OD tablet 90mg + 150mL of water  
• Arm 2: Brilinta OD tablet 90mg without water  
• Arm 3: Brilinta IR tablet (90mg) + 200mL 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 |
| Phase III (BE)  
NCT02400333 | Caucasian healthy volunteers | N = 36 | Single dose, Cross-Over  
• Arm 1: Brilinta OD tablet 90mg + 200mL of water  
• Arm 2: Brilinta OD tablet 90mg without water  
• Arm 3: Brilinta OD tablet 90mg (suspended in water) via nasogastric tube  
• Arm 4: Brilinta IR tablet 90mg + 200mL of water  
Local trial – One country | • BA/BE of Brilinta/Brilique Dispersible Tablet vs Brilinta/Brilique IR tablet | • FPD: Q2 2015  
• LPCD: Q3 2015  
• Completion date: Q3 2015  
• Top-line results: Q4 2015 |
| Phase II HESTIA2  
NCT02482298 | Patients with sickle cell disease | N = 90 | • Arm 1: Brilinta 10mg BID  
• Arm 2: Brilinta 45mg BID  
• Arm 3: Placebo BID  
Global trial – Eight countries | • Number of days with pain due to Sickle Cell Disease | • FPD: Q3 2015  
• LPCD: H2 2016  
• Estimated completion: H2 2016 |
# Farxiga (SGLT2 inhibitor)

## Diabetes

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Endpoints</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Phase IV</td>
<td>NCT02157298</td>
<td>Japanese patients with type-2 diabetes with inadequate glycemic control on insulin</td>
<td>N = 266</td>
<td>• Arm 1: Farxiga 5mg&lt;br&gt;• Arm 2: Placebo&lt;br&gt;Japan trial</td>
<td>• Change from baseline in Haemoglobin A1C (HbA1c) at week 16&lt;br&gt;• 1 year LT data</td>
</tr>
<tr>
<td>Phase III/IV</td>
<td>DECLARE NCT01730534</td>
<td>Type-2 diabetes mellitus with high risk for CV event</td>
<td>N = 17,276</td>
<td>• Arm 1: Farxiga 10mg QD + standard of care therapy QD&lt;br&gt;• Arm 2: Placebo + standard of care therapy for type-2 Diabetes&lt;br&gt;Global trial – 33 countries</td>
<td>• Time to first event included in the composite endpoint of CV death, MI or ischemic stroke</td>
</tr>
<tr>
<td>Phase III</td>
<td>NCT02096705</td>
<td>Asian subjects with type-2 diabetes who have inadequate glycemic control on insulin</td>
<td>N = 273</td>
<td>• Arm 1: Farxiga 10mg QD for 24 weeks + background Insulin&lt;br&gt;• Arm 2: Placebo QD for 24 weeks + background Insulin&lt;br&gt;Asian trial – three countries</td>
<td>• Change from baseline in HbA1c at week 24</td>
</tr>
<tr>
<td>Phase III</td>
<td>DERIVE NCT02413398</td>
<td>Patients with type-2 diabetes and moderate renal impairment</td>
<td>N = 302</td>
<td>• Arm 1: Farxiga 10mg QD for 24 weeks&lt;br&gt;• Arm 2: Placebo 10mg QD for 24 weeks&lt;br&gt;Global trial – five countries</td>
<td>• Change from baseline in HbA1c at week 24</td>
</tr>
<tr>
<td>Phase III</td>
<td>DEPICT 1 NCT02268214</td>
<td>Type-1 diabetes mellitus</td>
<td>N = 768</td>
<td>• Arm 1: Farxiga 5mg QD 52 weeks + insulin&lt;br&gt;• Arm 2: Farxiga 10mg QD 52 weeks + insulin&lt;br&gt;• Arm 3: Placebo QD 52 weeks + insulin&lt;br&gt;Global trial – 17 countries</td>
<td>Primary:&lt;br&gt;• Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at week 24</td>
</tr>
<tr>
<td>Phase III</td>
<td>DEPICT 2 NCT02460978</td>
<td>Type-1 diabetes mellitus</td>
<td>N = 768</td>
<td>• Arm 1: Farxiga 5mg QD 52 weeks + insulin&lt;br&gt;• Arm 2: Farxiga 10mg QD 52 weeks + insulin&lt;br&gt;• Arm 3: Placebo QD 52 weeks + insulin&lt;br&gt;Global trial – 14 countries</td>
<td>Primary:&lt;br&gt;• Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at week 24</td>
</tr>
</tbody>
</table>
# Onglyza (DPP-4 inhibitor)

## Type-2 Diabetes

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Endpoints</th>
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</tr>
</thead>
</table>
| Phase III   | Type-2 diabetes mellitus | N = 444 | • Arm 1: Onglyza 5mg QD + insulin with or without metformin  
              • Arm 2: Placebo QD + insulin with or without metformin  
              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: Q3 2015  
• Completed: Q1 2016  
• Top-line results: Q2 2016 |
| Phase III   | Type-2 diabetes mellitus | N = 639 | • Arm 1: Onglyza 5mg + Met (500mg with titration)  
              • Arm 2: Onglyza 5mg + Placebo  
              • Arm 3: Met (500mg 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: Q1 2016  
• Estimated completion date: H2 2016  
• Estimated top-line results: H2 2016 |
# Qtern (saxagliptin/dapagliflozin) (DPP-4/SGLT2 inhibitors)

## Diabetes

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<tr>
<th>Trial phase</th>
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</thead>
<tbody>
<tr>
<td>Phase III</td>
<td>Type-2 diabetes</td>
<td>N = 420</td>
<td>Arm 1: Saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR&lt;br&gt;Arm 2: Sitagliptin 100mg + 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: Q3 2015&lt;br&gt;Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td>Phase III</td>
<td>Type-2 diabetes</td>
<td>N = 440</td>
<td>Arm 1: Saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR&lt;br&gt;Arm 2: Glimperide 1-6mg + 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: H2 2016&lt;br&gt;Estimated top-line results: H2 2017</td>
</tr>
<tr>
<td>Phase III</td>
<td>Type-2 diabetes</td>
<td>N = 598</td>
<td>Arm 1: Saxagliptin 5mg + dapagliflozin 10mg + Met IR/XR 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: H2 2016&lt;br&gt;Estimated top-line results: H2 2017</td>
</tr>
<tr>
<td>Phase III</td>
<td>Type-2 diabetes</td>
<td>N = 900</td>
<td>Arm 1: Saxagliptin 5mg + dapagliflozin 5mg + Met IR/XR&lt;br&gt;Arm 2: Dapagliflozin 5mg + placebo + Met IR/XR&lt;br&gt;Arm 3: Saxagliptin 5mg + 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: H1 2017&lt;br&gt;Estimated top-line results: H2 2017</td>
</tr>
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</table>
## Bydureon (GLP-1 receptor agonist)
### Type-2 Diabetes

<table>
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<tr>
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<th>Number of patients</th>
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</thead>
</table>
| Phase IV          | EXSCEL             | N = 14,000         | • Arm 1: Bydureon once weekly 2mg SC  
• Arm 2: Placebo  
On a background of SoC medication, different degree of CV risk Global trial | • Time to first confirmed CV event in the primary composite CV endpoint (CV death, non-fatal MI, non-fatal stroke) | • FPD: Q2 2010  
• Estimated completion: 2018 |
|                  | NCT01144338        |                    |                                                                        |                                                                          |                                             |
|                  | Partnered          |                    |                                                                        |                                                                          |                                             |
| Phase III         | DURATION-NEO 1     | N = 375            | • Arm 1: Bydureon BID SC (autoinjector)  
• Arm 2: Bydureon weekly suspension SC (autoinjector)  
On a background of diet & exercise alone or with stable regimen of oral antidiabetics US only | • Change in HbA1c from baseline at 28 weeks | • FPD: Q1 2013  
• Completed: Q3 2014 |
|                  | NCT01652716        |                    |                                                                        |                                                                          |                                             |
|                  | Partnered          |                    |                                                                        |                                                                          |                                             |
| Phase III         | DURATION-NEO 2     | N = 360            | • Arm 1: Sitagliptin  
• Arm 2: Bydureon weekly suspension SC (autoinjector)  
• Arm 3: Placebo  
On a background of diet & exercise alone or with stable regimen of oral antidiabetics US only | • Change in HbA1c from baseline at 28 weeks | • FPD: Q1 2013  
• Completed: Q3 2014 |
|                  | NCT01652729        |                    |                                                                        |                                                                          |                                             |
|                  | Partnered          |                    |                                                                        |                                                                          |                                             |
| Phase III         | DURATION 7         | N = 440            | • Arm 1: Bydureon once weekly 2mg SC + Titrated Basal Insulin  
• Arm 2: Placebo + Titrated Basal Insulin  
Double-blind 1:1 randomisation. Background therapy with or without Metformin Global trial | • Change in HbA1c from baseline at 28 weeks | • FPD: Q3 2014  
• LPCD: H2 2016  
• Estimated completion: H2 2016 |
|                  | NCT02229383        |                    |                                                                        |                                                                          |                                             |
|                  | Partnered          |                    |                                                                        |                                                                          |                                             |
| Phase III         | DURATION 8         | N = 660            | • Arm 1: Bydureon once weekly 2mg SC  
• Arm 2: Dapagliflozin 10mg  
• Arm 3: Bydureon once weekly 2mg SC + dapagliflozin 10mg  
Double-blind 1:1:1 randomisation. Background therapy with Metformin 1500mg/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 |
|                  | NCT02229396        |                    |                                                                        |                                                                          |                                             |
## Epanova (omega-3 carboxylic acids)
### Hypertriglyceridaemia

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

## Hypertriglyceridaemia

<table>
<thead>
<tr>
<th>Trial phase</th>
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<tbody>
<tr>
<td><strong>Phase I</strong> Microsphere bioavailability NCT02359045</td>
<td>Healthy volunteers</td>
<td>N = 40 Part A N = 42 Part B</td>
<td>• Arm 1: D1400147 4g • Arm 2: D14000136 4g • Arm 3: D14000137 4g • Arm 4: Epanova 4g Local trial – one country</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><strong>Phase I</strong> Japanese food interaction NCT02372344</td>
<td>Healthy male volunteers</td>
<td>N = 42</td>
<td>• Epanova 4g X 3 separate occasions (fasting, before meal, and after meal) Local trial – one country</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><strong>Phase I</strong> SAD/MAD NCT02209766</td>
<td>Healthy male Japanese and Caucasian subjects</td>
<td>N = 18</td>
<td>• Arm 1: (Japanese): Epanova 2g vs. Placebo QD • Arm 2: (Japanese): Epanova 4g vs Placebo QD • Arm 3: (Caucasian): Epanova 4g vs Placebo Local trial – one country</td>
<td>• PK of single and multiple doses in healthy male Japanese subjects • Safety/tolerability profile</td>
<td>• FPD: Q3 2014 • LPCD: Q4 2014 • Completed: Q3 2015</td>
</tr>
<tr>
<td><strong>Phase I</strong> NCT02189252</td>
<td>Patients with a history of pancreatitis</td>
<td>N = 16</td>
<td>• Arm 1: Epanova 4g —omega-3-acid ethyl esters capsules 4g QD • Arm 2: omega-3-acid ethyl esters capsules 4g —Epanova 4g QD • Arm 3: Epanova 2g —omega-3-acid ethyl esters capsules 4g QD • Arm 4: omega-3-acid ethyl esters capsules 4g —Epanova 2g QD Global trial – two countries</td>
<td>• Plasma concentration vs. time curve (AUCD-24) [Time Frame: 0 to 24 hours (AUCD-24)]</td>
<td>• FPD: Q3 2014 • LPCD: Q2 2015 • Completed: Q4 2015</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>
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<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 500mg monthly IM + an additional dose on d14 (+ oral placebo)  
Arm 2: Arimidex 1mg (+ placebo injection)  
Global trial – 21 countries | • PFS  
• OS is a secondary endpoint | • FPD: Q4 2012  
• LPCD: Q3 2014  
• 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>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;SOLO-2 Partnered&lt;br&gt;NCT01874353</td>
<td>PSR BRCAm ovarian cancer</td>
<td>N = 264</td>
<td>• Arm 1: Lynparza tablets 300mg BID as maintenance therapy until progression&lt;br&gt;• Arm 2: placebo tablets BID Global trial</td>
<td>• PFS&lt;br&gt;• OS secondary endpoint</td>
<td>• FPD: Q3 2013&lt;br&gt;• LPCD: Q4 2014&lt;br&gt;• Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;SOLO-1 Partnered&lt;br&gt;NCT01844986</td>
<td>1L maintenance BRCAm ovarian cancer</td>
<td>N = 344</td>
<td>• Arm 1: Lynparza tablets 300mg BID maintenance therapy for 2 years or until disease progression&lt;br&gt;• Arm 2: placebo</td>
<td>• PFS&lt;br&gt;• OS secondary endpoint</td>
<td>• FPD: Q3 2013&lt;br&gt;• LPCD: Q1 2015&lt;br&gt;• Estimated top-line results: H2 2017</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;SOLO-3&lt;br&gt;NCT02282020</td>
<td>PSR gBRCAm ovarian cancer 3L+ Line</td>
<td>N = 411</td>
<td>• Arm 1: Lynparza 300mg BID to progression&lt;br&gt;• Arm 2: Physician’s choice (single agent chemotherapy) Global trial</td>
<td>• PFS&lt;br&gt;• OS secondary endpoint</td>
<td>• FPD: Q1 2015&lt;br&gt;• LPCD: H2 2017&lt;br&gt;• Estimated top-line results: 2018</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;GOLD&lt;br&gt;NCT01924533</td>
<td>2L gastric cancer (all patients with a co-primary)</td>
<td>N = 525</td>
<td>• Arm 1: paclitaxel + Lynparza until progression&lt;br&gt;• Arm 2: paclitaxel + placebo&lt;br&gt;Lynparza dose 100mg BID throughout paclitaxel dose cycle &amp; 300mg BID post cycle Asian trial</td>
<td>• OS</td>
<td>• FPD: Q3 2013&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Top-line results reported: Q2 2016&lt;br&gt;• Primary endpoint not met&lt;br&gt;• Full data to be presented at upcoming medical conference</td>
</tr>
<tr>
<td><strong>Phase I / II</strong>&lt;br&gt;MEGLIO&lt;br&gt;NCT02734004</td>
<td>gBRCAm ovarian cancer 3L&lt;br&gt;gBRCAm HER2-negative breast cancer 1-3L&lt;br&gt;Small cell lung cancer 2L+&lt;br&gt;ATM-negative gastric cancer 2L+</td>
<td>N = 139</td>
<td>• Arm 1: Lynparza tablets 300mg BID starting on week 1 day 1 / durvalumab IV 1.5g every 4 weeks starting on week 5 day 1. Dose until progression. Global trial</td>
<td>Primary endpoints&lt;br&gt;Secondary endpoints</td>
<td>• FPD: Q2 2016&lt;br&gt;• LPCD: Q4 2016&lt;br&gt;• Estimated top-line results: 2018</td>
</tr>
</tbody>
</table>
## Lynparza (PARP inhibitor)

### Solid tumours

<table>
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<tr>
<th>Trial phase</th>
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</tr>
</thead>
</table>
| **Phase III OlympiAD**<br>NCT02000622 | BRCAm metastatic breast cancer | N = 310 | • Arm 1: Lynparza 300mg BID, continuous to progression  
• Arm 2: Physician’s choice: capecitabine 2500mg/m² x 14 q 21  
vinorelbine 30mg/m² d 1, 8 q 21  
eribulin 1.4mg/m² d 1, 8 q 21 to progression  
Global trial | • PFS  
• Secondary endpoint: OS | • FPD: Q2 2014  
• LPCD: Q4 2015  
• Estimated top-line results: H2 2016 |
| **Phase III OlympiA Partnered**<br>NCT02032823 | BRCAm adjuvant breast cancer | N = 1,500 | • Arm 1: Lynparza 30mg BID  
12 month duration  
• Arm 2: Placebo 12 month duration  
Global trial partnership with BIG and NCI/NCRG | • Invasive Disease Free Survival (IDFS)  
• Secondary endpoint: Distant Disease Free Survival and OS | • FPD: Q2 2014  
• LPCD: 2018  
• Estimated top-line results: 2020 |
| **Phase III POLO**<br>NCT02184195 | Pancreas gBRCA | N = 145 | • Arm 1: Lynparza tablets 300mg twice daily as maintenance therapy until progression.  
• Arm 2: Placebo tablets BID  
Global trial | • Primary endpoint: PFS  
• Secondary endpoint: OS | • FPD: Q1 2015  
• LPCD: H2 2017  
• Estimated top-line results: 2018 |
| **Phase II**<br>NCT01972217 | 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>
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</tr>
</thead>
</table>
| Phase III AURA3 | Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M | N = 410 | • Arm 1: Tagrisso 80mg QD  
• Arm 2: pemetrexed 500mg/m² + carboplatin AUC5 or pemetrexed 500mg/m² + cisplatin 75mg/m² (2:1 randomisation)  
Global trial | • PFS  
• OS and QoL as secondary endpoints | • FPD: Q3 2014  
• Enrolment complete  
• Estimated primary completion: H2 2016 |
| Phase III FLAURA | Advanced EGFRm NSCLC 1L | N = 530 | • Arm 1: Tagrisso 80mg  
• Arm 2: erlotinib 150mg or Iressa 250mg (dealers choice); 1:1 randomisation  
Global trial | • PFS  
• OS and QoL as secondary endpoints | • FPD: Q1 2015  
• Estimated completion: 2017 |
| Phase III ADAURA | Adjuvant EGFRm NSCLC | N = 700 | • Arm 1: Tagrisso 80mg QD following complete tumour resection, with or without chemotherapy  
• Arm 2: Placebo  
Global trial | • DFS  
• DFS Rate, OS, OS Rate, QoL | • FPD: Q4 2015  
• Estimated completion: 2022 |
| Phase III CAURAL | Adjuvant EGFRm NSCLC | N = 350 | • Arm 1: Tagrisso (80mg QD) + durvalumab (10mg/kg q2w (IV) infusion)  
• Arm 2: Tagrisso (80mg QD)  
Global trial | • PFS  
• ORR, OS, QoL as secondary endpoints | • FPD: Q3 2015  
• Enrolment hold implemented in Q4 2015 will not restart |
| Phase II AURA17 | Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M | N = 175 | • Tagrisso 80mg QD  
Asia Pacific Regional trial | • ORR  
• PFS and OS secondary endpoints | • FPD: Q3 2015  
• Enrolment complete  
• Primary completion: Q2 2016 |
| Phase II AURA2 | Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M | N = 175 | • Tagrisso 80mg QD  
Global trial | • ORR  
• PFS and OS secondary endpoints | • FPD: Q2 2014  
• Enrolment complete (N = 210) |
| Phase III AURA | Advanced EGFRm NSCLC TKI failure + / primary resistance mutation T790M | N ~ 500 | • Dose escalation trial  
• Ph II Extension cohort (T790M only) Tagrisso 80mg QD  
Global trial | • Safety and tolerability  
• ORR  
• PFS and OS secondary endpoints | • FPD: Q1 2013  
• Enrolment complete (N = 201 in extension portion) |
# Tagrisso (Highly-selective, irreversible EGFR TKI)

Non-small cell lung cancer (NSCLC)

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</table>
| Phase Ib TATTON NCT02143466 | Advanced EGFRm NSCLC TKI failure | N=90 | • Arm 1: Tagrisso + durvalumab  
• Arm 2: Tagrisso + savolitinib  
• Arm 3: Tagrisso + selumetinib  
Global trial | Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity | • FPD: Q3 2014  
• Dose escalation completed  
• Dose expansions ongoing  
• Enrolment to durvalumab combo arms will not restart |
| Phase I BLOOM NCT02228369 | EGFRm NSCLC, CNS disease | N = 47 | • MAD  
• Expansion in LM patients at RP2D with AZD3759  
• Expansion in LM patients at 160mg with Tagrisso including cohort with T790M NSCLC  
Global trial – four countries | Safety and tolerability  
Preliminary anti-tumour activity | • FPD: Q4 2014  
• Estimated primary completion: H1 2017 |
### Serious infections

**Zavicefta (BLI/cephalosporin SBI)**

<table>
<thead>
<tr>
<th>Trial phase</th>
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</tr>
</thead>
</table>
| Phase III RECLAIM-3 (NCT01726023) | Hospitalised patients with complicated intra-abdominal infections | N = 486 | • Arm 1: Zavicefta 2000/500mg plus Metronidazole IV  
• Arm 2: Meropenem IV  
Asia-focused trial – three countries (China, Vietnam & Korea) | • Clinical Cure at the TOC visit in the MITT analysis set | • FPD: Q1 2013  
• LPCD: Q1 2015  
• Top-line results: Q3 2015 |
| Phase III REPROVE (NCT01808092) | Hospitalised patients with nosocomial pneumonia infections, including hospital acquired pneumonia (HAP) and ventilator associated pneumonia (VAP) | N = 1,000 | • Arm 1: Zavicefta 2000/500mg IV  
• Arm 2: Meropenem IV  
Global trial – 24 countries | • Proportion of patients with clinical cure at the TOC visit in the cMITT and CE analysis sets (co-primary analyses) | • FPD: Q2 2013  
• LPCD: Q4 2015  
• Top-line results: Q3 2016 |
# Zavicefta (BLI/cephalosporin SBI)

## Serious Infections

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
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<th>Status</th>
</tr>
</thead>
</table>
| Phase III  | RECLAIM-1                                               | N = 493            | • Arm 1: Zavicefta 2000/500mg plus Metronidazole IV 
  • Arm 2: Meropenem IV 
  Global Trial– 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                                               | N = 577            | • Arm 1: Zavicefta 2000/500mg plus Metronidazole IV 
  • Arm 2: Meropenem IV 
  Global Trial– 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                                             | N = 563            | • Arm 1: Zavicefta 2000/500mg IV plus either 500mg of oral ciprofloxacin or 800mg/160mg of oral sulfamethoxazole/trimethoprim 
  • Arm 2: Doripenem 500mg IV plus either 500mg of oral ciprofloxacin or 800mg/160mg 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                                             | N = 583            | • Arm 1: Zavicefta 2000/500mg IV plus either 500mg of oral ciprofloxacin or 800mg/160mg of oral sulfamethoxazole/trimethoprim 
  • Arm 2: Doripenem 500mg IV plus either 500mg of oral ciprofloxacin or 800mg/160mg 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                                                | N = 345            | • Arm 1: Zavicefta 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                                            |                    |                                                                      |                                                                          |                                     |
## Nexium
### Gastrointestinal

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
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<th>Endpoints</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Phase III</td>
<td>Seriously ill patients with at least one major risk factor for stress ulcer related bleeding (Stress Ulcer Prophylaxis)</td>
<td>N = 300</td>
<td>• Arm 1: Nexium 40mg bid intermittent iv infusions given for max. 14 days&lt;br&gt;• Arm 2: Cimetidine 300mg bolus iv infusion followed by continuous iv infusion 50mg/h for a maximum of 14 days&lt;br&gt;China-only trial</td>
<td>• Clinically significant upper GI bleeding</td>
<td>• FPD: Q3 2014&lt;br&gt;• LPCD: Q1 2016&lt;br&gt;• Completed: Q2 2016</td>
</tr>
</tbody>
</table>
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                         | N = 661            | Arm 1: 210mg brodalumab SC  
Arm 2: 140mg brodalumab SC  
Arm 3: Placebo SC             | PASI at week 12  
Static physician’s global assessment (sPGA) at wk 12                   | Completed - Partnered                                                     |
| NCT01708590   | Moderate to severe plaque psoriasis |                    |                                                                        |                                                                           |                               |
| Phase III     | AMAGINE-2                         | N = 1,800          | Arm 1: 210mg brodalumab SC  
Arm 2: 140mg brodalumab SC  
Arm 3: 45 or 90mg ustekinumab SC  
Arm 4: Placebo SC             | PASI at week 12  
Static physician’s global assessment (sPGA) at wk 12                   | Completed - Partnered                                                     |
| NCT01708603   | Moderate to severe plaque psoriasis |                    |                                                                        |                                                                           |                               |
| Phase III     | AMAGINE-3                         | N = 1,881          | Arm 1: 210mg brodalumab SC  
Arm 2: 140mg brodalumab SC  
Arm 3: 45 or 90mg ustekinumab SC  
Arm 4: Placebo SC             | PASI at week 12  
Static physician’s global assessment (sPGA) at wk 12                   | Completed - Partnered                                                     |
| NCT01708629   | Moderate to severe plaque psoriasis |                    |                                                                        |                                                                           |                               |
## Benralizumab (IL-5R mAb)

### Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;CALIMA&lt;br&gt;NCT01914757</td>
<td>Severe asthma, inadequately controlled despite background controller medication, MD &amp; HD ICS + LABA ± chronic OCS Age 12 – 75 years</td>
<td>N = 1,026 HD + ~200 MD</td>
<td>• Arm 1: 30mg Q6w SC&lt;br&gt;• Arm 2: 30mg Q4w SC&lt;br&gt;• Arm 3: Placebo SC 56-week trial Global trial – 11 countries</td>
<td>• Annual asthma exacerbation rate&lt;br&gt;• Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM</td>
<td>FPD: Q4 2013&lt;br&gt;Completed: Q2 2016</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;SIROCCO&lt;br&gt;NCT01928771</td>
<td>Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA ± chronic OCS Age 12 – 75 years</td>
<td>N = 1,134</td>
<td>• Arm 1: 30mg Q8w SC&lt;br&gt;• Arm 2: 30mg Q4w SC&lt;br&gt;• Arm 3: Placebo SC 48-week trial Global trial – 17 countries</td>
<td>• Annual asthma exacerbation rate&lt;br&gt;• Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalisation visits, PK, and IM</td>
<td>FPD: Q4 2013&lt;br&gt;Completed: Q2 2016</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;ZONDA&lt;br&gt;NCT02075255</td>
<td>Severe asthma, inadequately controlled on HD ICS plus long-acting β2 agonist and chronic oral corticosteroid therapy Age 18 – 75 years</td>
<td>N = 210</td>
<td>• Arm 1: 30mg Q8w SC&lt;br&gt;• Arm 2: 30mg Q4w SC&lt;br&gt;• Arm 3: Placebo SC 46-week trial Global trial – 12 countries</td>
<td>• Reduction of oral corticosteroid dose</td>
<td>FPD: Q3 2014&lt;br&gt;Estimated completion: H2 2016</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;Meltimi&lt;br&gt;NCT02808819</td>
<td>A multicenter, open-label, safety extension trial with Benralizumab (MEDI-563) for asthmatic adults on Inhaled Corticosteroid plus Long-acting β2 Agonist (MELTEMI) Age 18 – 75 years</td>
<td>N = 770</td>
<td>• Arm 1: 30mg Q4W SC&lt;br&gt;• Arm 2: 30mg Q6W SC</td>
<td>• Safety and tolerability</td>
<td>FPD: H2 2016&lt;br&gt;Estimated completion: 2019</td>
</tr>
<tr>
<td><strong>Phase III</strong>&lt;br&gt;ALIZE</td>
<td>A multicenter, randomized, double-blind, parallel group, placebo-controlled, Phase 3b trial to evaluate the potential effect of Benralizumab on the humoral immune response to the seasonal influenza vaccination in adolescent and young adult patients with severe asthma Ages 12-21 years</td>
<td>N = 100</td>
<td>• Arm1 30mg Q4W SC with 1 dose of seasonal influenza virus vaccine Intramuscular (IM) at week 8.&lt;br&gt;• Arm1 Placebo Q4W SC with 1 dose of seasonal influenza virus vaccine Intramuscular (IM) at week</td>
<td>• Post-dose strain-specific hemagglutination-inhibition (HAI) antibody geometric mean fold rises (GMFRs)&lt;br&gt;• Post-dose strain-specific serum HAI antibody geometric mean titers (GMTs)&lt;br&gt;• Proportion of patients who experience a strain-specific post-dose antibody response with antibody response defined as a ≥4-fold rise in HAI antibody titer</td>
<td>FPD: H2 2016&lt;br&gt;Estimated completion: 2019</td>
</tr>
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</table>
## Benralizumab (IL-5R mAb)

### Asthma

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<tr>
<th>Trial phase</th>
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</thead>
</table>
| **Phase III**  
BISE  
NCT02322775 | Asthmatic with FEV1 (50-80% predicted) on low to medium dose inhaled corticosteroid  
Age 18 – 75 years | N = 200 | • Arm 1: 30mg Q4W SC  
• Arm 3: Placebo SC  
12-week trial  
Global trial – six countries | • Pulmonary function (FEV1) | • FPD: Q1 2015  
• Completed: Q1 2016 |
| **Phase III**  
GORA  
NCT02258542 | Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS  
Age 12 – 75 years | N = 2,550 | • Arm 1: 30mg Q4W SC  
• Arm 2: 30mg Q8W SC*  
* Placebo administered at select interim visits to maintain blind between treatment arms  
56-week (adults)  
108-week (adolescents)  
Global trial | • Safety and tolerability | • FPD: Q4 2014  
• Estimated completion: 2018 |
| **Phase III**  
GREGALE  
NCT02417961 | Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS  
Age 18 – 75 years | N = 120 | • Arm 1: 30mg Q4W SC  
28-week (adults)  
Global trial – two countries | • Functionality, reliability, and performance of a pre-filled syringe With Benralizumab Administered at Home | • FPD: Q2 2015  
• Completed: Q2 2016 |
| **Ph III**  
ARIA  
NCT02821416 | A Double-Blind, Randomized, Parallel Group, Placebo-Controlled Multi-Centre Trial to Evaluate the effect of Benralizumab on Allergen-Induced Inflammation in Mild, Atopic Asthmatic  
Age 18 – 65 years | N = 38 | • Arm1 : 30mg Q4W SC  
• Arm2: Placebo SC | • Safety and tolerability | • H2 2016  
• Estimated completion 2019 |
### Benralizumab (IL-5R mAb)

**Chronic Obstructive Pulmonary Disease (COPD)**

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Design</th>
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</tr>
</thead>
</table>
| Phase III    | Moderate to very severe COPD with exacerbation history   | N = 2,168          | • Arm 1: 10mg Q8W SC  
• Arm 2: 30mg Q4W SC  
• Arm 3: 100mg Q8W SC  
• Arm 4: Placebo SC  
48-week trial  
Global trial – 23 countries   | • 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: 30mg Q4W SC  
• Arm 2: 100mg Q8W SC  
• Arm 3: Placebo SC  
48-week trial  
Global trial – 17 countries   | • Rate of COPD exacerbation                              | • FPD: Q3 2014  
• Estimated completion: 2018 |
| GALATHEA     |                                                          |                    |                                                                       |                                  |                               |
| NCT02138916  |                                                          |                    |                                                                       |                                  |                               |
### 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 320/9.6μg BID  
• BFF MDI 160/9.6μg BID  
• BFF MDI 80/9.6μg BID  
• BD MDI 320μg BID  
• FF MDI 9.6μg BID  
Randomised, 4-period, 5-treatment incomplete-block and cross-over  
Estimated time from FSFV to DBL is approximately seven months. US | • Forced expiratory volume in 1 second area under the curve from 0 to 12 hours (FEV₁ AUC₀⁻¹₂)  
• LPCD: Q3 2014  
• Top-line results: Q2 2015* | * Clinically completed |
| (BFF Dose-ranging)           |                               |                   |                                                                                                                        |                                                                            |                                                                        |
| NCT02196077                  |                               |                   |                                                                                                                        |                                                                            |                                                                        |
## PT010 (LABA/LAMA/ICS)
### Chronic Obstructive Pulmonary Disease (COPD) & Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Phase III (Long-term BMD and Ocular Safety) NCT02536508</td>
<td>Moderate to very severe COPD</td>
<td>N = 500</td>
<td>Treatments (52-week Treatment Period) • BGF MDI 320/14.4/9.6µg • GFF MDI 14.4/9.6µg • BFF MDI 320/9.6µg • Symbicort TBH 400/12µg Randomised, double-blind, chronic-dosing, multi-centre Estimated time from FSFV to DBL is approximately 21 months, Country – US</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 Ocular Sub-study Safety Endpoint: • Change from baseline in LOCS III at week 52</td>
<td>• FSD: Q3 2015 • LPCD: H2 2016 • Estimated top-line results: H1 2017</td>
</tr>
<tr>
<td>Phase III (Exacerbation trial) ETHOS NCT02465567</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) • BGF MDI 320/14.4/9.6µg BID • BGF MDI 160/14.4/9.6µg BID • BFF MDI 320/9.6µg BID • GFF MDL 14.4/9.6µg BID Randomised, double-blind, multi-centre and parallel-group Estimated time from FSFV to DBL is approximately three years Multi-country</td>
<td>• Rate of moderate or severe COPD exacerbations • Time to first moderate or severe COPD exacerbation</td>
<td>• FPD: Q3 2015 • LPCD: H2 2016 • Estimated top-line results: H2 2018</td>
</tr>
<tr>
<td>Phase III (Lung function trial) KRONOS NCT02497001</td>
<td>Moderate to very severe COPD</td>
<td>N = 1,800</td>
<td>Treatments (24-week Treatment Period) • BGF MDI 320/14.4/9.6µg • GFF MDI 14.4/9.6µg • BFF MDI 320/9.6µg • Symbicort TBH 400/12µg Randomised, double-blind, parallel-group, and chronic dosing and multi-centre Estimated time from FSFV to DBL is approximately two years Multi-country</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 and BGF MDI vs Symbicort TBH) • Change from baseline in morning pre-dose trough FEV1 over 24 weeks (BGF MDI vs BFF MDI) • Transition dyspnea index (TDI) focal score over 24 weeks (BGF MDI vs BFF MDI and BGF MDI vs GFF MDI) Primary Endpoint (Japan): • Change from baseline in morning pre-dose trough FEV1 over 24 weeks (BGF MDI vs BFF MDI, BGF MDI vs GFF MDI) Primary Endpoint (US): • FEV1 area under curve from 0 to 4 hours (AUC0-4) at week 24 (BGF MDI vs BFF MDI) • Change from baseline in morning pre-dose trough FEV1 at week 24 (MDI vs GFF MDI)</td>
<td>• FPD: Q3 2015 • LPCD: H2 2016 • Estimated top-line results: H2 2017</td>
</tr>
</tbody>
</table>
## PT010 (LABA/LAMA/ICS)
### Chronic Obstructive Pulmonary Disease (COPD) & Asthma

<table>
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<tr>
<th>Trial phase</th>
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</thead>
</table>
| **Phase II (BD Dose-ranging in Asthma)**         | Adult mild to moderate persistent asthma  | N = 150            | • Arm 1: BD MDI 320μg BiD  
• Arm 2: BD MDI 160μg BiD  
• Arm 3: BD MDI 80μg BiD  
• Arm 4: BD MDI 40μg BiD  
• Arm 5: Placebo MDI BiD  
Randomised, 4-period, 5-treatment incomplete-block and cross-over  
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  
• LPD: Q1 2015  
• Top-line results: Q3 2015  
* Clinically completed |
| **NCT02105012**                                  |                                           |                    |                                                                                                   |                                                                                                                                                                  |                                             |
| **Phase II (GP Dose-ranging in Asthma)**         | Intermittent asthma/mild to moderate persistent asthma | N = 200            | Treatment (18-week Treatment Period)  
• GP MDI 28.8μg BiD  
• GP MDI 14.4μg BiD  
• GP MDI 7.2μg BiD  
• GP MDI 3.6μg BiD  
• Seferent® 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  
• LPD: Q4 2015  
• Top-line results: Q2 2016*  
*Clinically completed |
| **NCT02433834**                                  |                                           |                    |                                                                                                   |                                                                                                                                                                  |                                             |
## PT010 (LABA/LAMA/ICS)

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

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
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<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I (BGF PK trial)</td>
<td>Healthy volunteers</td>
<td>N = 60</td>
<td>• Arm 1: BGF MDI 320/14.4/9.6μg</td>
<td>• Overall safety</td>
<td>• FPD: Q3 2014</td>
</tr>
<tr>
<td>NCT02189304</td>
<td></td>
<td></td>
<td>• Arm 2: BFF MDI (320/9.6μg)</td>
<td>• PK parameters AUC0–12 and Cmax</td>
<td>* Clinically completed</td>
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<tr>
<td></td>
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<td></td>
<td>• Arm 3: Symbicort Turbuhaler 400/12μg</td>
<td>• Top-line results: Q4 2014*</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Randomised, double-blind, single-dose, 3-period, 3-treatment and cross-over</td>
<td>Estimated time from FSFV to DBL is approximately three months US</td>
<td></td>
</tr>
<tr>
<td>Phase I (BGF PK in Japanese Subjects)</td>
<td>Japanese healthy volunteers</td>
<td>N = 28</td>
<td>Treatment (2-week Treatment Period)</td>
<td>• Overall safety</td>
<td>• FPD: Q3 2014</td>
</tr>
<tr>
<td>NCT02197975</td>
<td></td>
<td></td>
<td>• Arm 1: BGF MDI 160/14.4/9.6μg</td>
<td>• PK parameters AUC0–12 and Cmax</td>
<td>* Clinically completed</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Arm 2: BGF MDI 160/14.4/9.6μg</td>
<td>• Top-line results: Q4 2014*</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Arm 3: Placebo MDI</td>
<td>* Clinically completed</td>
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<tr>
<td></td>
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<td></td>
<td>Randomised, double-blind, placebo-controlled, 2-period, ascending-dose and crossover</td>
<td>Estimated time from FSFV to DBL is approximately eight weeks Japan</td>
<td></td>
</tr>
<tr>
<td>Phase I (GFF PK in Japanese Subjects)</td>
<td>Japanese healthy volunteers</td>
<td>N = 24</td>
<td>Treatment (4-day Treatment Period)</td>
<td>• Overall safety</td>
<td>• FPD: Q3 2014</td>
</tr>
<tr>
<td>NCT02196714</td>
<td></td>
<td></td>
<td>• Arm 1: GFF MDI 14.4/9.6μg</td>
<td>• PK parameters AUC0–12 and Cmax</td>
<td>* Clinically completed</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Arm 2: GFF MDI 28.8/9.6μg</td>
<td>• Top-line results: Q4 2014*</td>
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<tr>
<td></td>
<td></td>
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<td>• Arm 2: GP MDI 14.4μg</td>
<td>* Clinically completed</td>
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<tr>
<td></td>
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<td></td>
<td>• Arm 2: GP MDI 28.8μg</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Randomised, double-blind, single-dose, 4-period, 4-treatment and cross-over</td>
<td>Estimated time from FSFV to DBL is approximately 13 weeks Japan</td>
<td></td>
</tr>
</tbody>
</table>
# Tralokinumab (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>
</table>
| Phase III STRATOS 1 NCT02161757 | 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 NCT02194699 | 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 NCT02281357 | 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 NCT02449473 | 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 sub-mucosal eosinophils  
Secondary:  
• Change in blood eosinophils levels  
• Change in eosinophil cationic protein as a measure of activated eosinophils in blood and sputum | • FPD: Q3 2015  
• LPCD: 2017  
• Estimated completion date: 2018  
• Estimated top-line results: 2018 |
## 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>
</table>
| Phase II    | Adults with atopic dermatitis | N = 306 | • Arm 1: Tralokinumab dose 45mg SC  
• Arm 2: Tralokinumab dose 150mg SC  
• Arm 3: Tralokinumab dose 300mg SC  
• Arm 4: Placebo SC  
Global trial – six countries | • Change from baseline in SCORAD at week 12  
Key Secondary Endpoints:  
• Percentage of subjects achieving IGA of 0 or 1  
• Change from baseline in EASI  
• Percentage of subjects achieving EASI50 and SCORAD50  
• Change from baseline in pruritis  
• Safety and tolerability  
• Tralokinumab serum concentration | • FPD: Q1 2015  
• LPCD: Q4 2015  
• Completion date: Q1 2016  
• Top-line results: Q1 2016 |

**NCT02347176**
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>
</table>
| Phase III  | Moderate to severe SLE TULIP SLE 1 | N = 450 | • Arm 1: 300mg IV MEDI-546 Q4W for 48 weeks  
• Arm 2: 150mg IV MEDI-546 Q4W for 48 weeks  
• Arm 3: Placebo IV Q4W for 48 weeks | Response in SLE responder index at week 52 | • FPD: Q3 2015  
• LPCD: 2018  
• Estimated top-line results: 2018 |
| Phase III  | Moderate to severe SLE TULIP SLE 2 | N = 360 | • Arm 1: 300mg IV MEDI-546 Q4W for 48 weeks  
• Arm 2: 150mg IV MEDI-546 Q4W for 48 weeks | Response in SLE responder index at week 52 | • FPD: Q3 2015  
• LPCD: 2018  
• Estimated top-line results: 2018 |
| Phase II   | Moderate to severe SLE patients | N = 307 | • Arm 1: 300mg IV MEDI-546 Q4W for 48 weeks  
• Arm 2: 1000mg IV MEDI-546 Q4W for 48 weeks  
• Arm 3: Placebo IV Q4W for 48 weeks | Response in SLE responder index at 6 months | • FPD: Q1 2012  
• Top-line results: Q3 2014 |
| Phase II   | Moderate to severe SLE patients | N = 218 | • Arm 1: MEDI-546, IV Q4W for 104 weeks | Open-label extension to evaluate long-term safety and tolerability | • FPD: Q1 2013  
• Estimated top-line results: 2017 |
| Phase II   | Japanese SLE patients | N = 17 | Open-label, dose escalation trial:  
• Arm 1: 100mg IV Q4W for 48 weeks then 300mg IV Q4W for 104 weeks  
• Arm 2: 300mg IV Q4W for 48 weeks then 300mg IV Q4W for 104 weeks  
• Arm 3: 1000mg IV Q4W for 48 weeks then1000mg IV Q4W for 104 weeks | Safety, tolerability, PK/PD | • Top-line results: Q1 2015 |
| Phase I    | Healthy volunteers | N = 30 | • Arm 1: 300mg SC single dose  
• Arm 2: 300mg IV single dose  
• Arm 3: 800 mg SC single dose | Safety, tolerability, PK/PD | • FPD: Q4 2015  
• LPCD: H1 2016  
• Estimated top-line results: H2 2016 |
Anifrolumab (type I IFN receptor mAb)
Lupus Nephritis (LN)

<table>
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<tr>
<th>Trial phase</th>
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<th>Number of patients</th>
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<th>Endpoints</th>
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</tr>
</thead>
</table>
| Phase II    | Active Proliferative LN (TULIP-LN1) | N = 150 | Arm 1: 900 mg IV Q4W for 12 weeks then 300mg 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 |

NCT02547922
# 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    | Rheumatoid Arthritis | N = 31             | • Arm A: Acalabrutinib + methotrexate  
• Arm B: Methotrexate | Disease Activity Score 28-CRP at week 4 | • FPD: Q2 2015  
• LPCD: Q2 2016  
• Estimated Completion: H1 2017 |
| ACE-RA-001  | NCT02387762        |                    |        |             |        |
## Roxadustat (HIF-PHI)

### Chronic Kidney Disease/End Stage Renal Disease (CKD/ESRD)

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Endpoints</th>
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</tr>
</thead>
</table>
| **Phase III ANDES**
NCT01750190 | Anaemia in CKD patients not receiving dialysis | N = 600 | • Arm 1: Roxadustat  
• Arm 2: Placebo  
Global trial | 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 | 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 | 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 | 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 | 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 | 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 | Haemoglobin response | • FPD: Q4 2014  
• Estimated completion: 2017  
Sponsored by Astellas |
Roxadustat (HIF-PHI)

Chronic Kidney Disease/End Stage Renal Disease (CKD/ESRD)

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<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III       | Anaemia in newly initiated dialysis patients| N = 1,000          | • Arm 1: Roxadustat  
• Arm 2: Epoetin alfa  
Global trial                                                                 | Haemoglobin response       | • FPD: Q4 2013  
• Estimated completion: 2017  
Sponsored by FibroGen                                                   |
| Himalayas       |                                             | NCT02652310        |                                                                                                                                         |                             |                                                                        |
| Phase III       | Anaemia in CKD patients not receiving dialysis| N = 150            | Arm 1: FG-4592 (roxadustat)  
Arm 2: Placebo  
China trial                                                                 | Haemoglobin response       | • FPD: Q4 2015  
• Estimated completion: 2017  
Sponsored by FibroGen                                                   |
| NCT02652819     |                                             |                    |                                                                                                                                         |                             |                                                                        |
| Phase III       | Anaemia in CKD patients receiving dialysis  | N = 300            | Arm 1: FG-4592 (roxadustat)  
Arm 2: Epoetin alfa  
China trial                                                                 | Haemoglobin response       | • FPD: Q4 2015  
• Estimated completion: 2017  
Sponsored by FibroGen                                                   |
| NCT02652806     |                                             |                    |                                                                                                                                         |                             |                                                                        |
# Durvalumab (MEDI4736; PD-L1 mAb)

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

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Design</th>
<th>Endpoints</th>
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</thead>
<tbody>
<tr>
<td>HAWK</td>
<td>NCT02207530</td>
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<td>NCT02301130</td>
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<td>Partnered with KHK</td>
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<tr>
<td>NCT01938812</td>
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- Trial conducted in Japan
# 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 III** | **ARCTIC** NCT02352948 | Stage IIIIB-IV 3L NSCLC patients who have not be tested positive for EGFR/ALK mutation | N = 480 | • Arm 1: Durvalumab + tremelimumab (PD-L1 –ve patients)  
• Arm 2: Standard of Care  
• Arm 3: tremelimumab (PD-L1 –ve patients)  
• Arm 4: Durvalumab (PD-L1 –ve patients) | • PFS  
• OS  
• Safety | Combination therapy  
• FPD: Q2 2015  
• LPCD: Q3 2016  
• Estimated completion: 2017 (PFS, OS) |
| **Phase III** | **MYSTIC** NCT02453282 | NSCLC 1L | N = 1,092 | • Arm 1: Durvalumab  
• Arm 2: Durvalumab + tremelimumab  
• Arm 3: Standard of care | • PFS  
• OS  
• Safety | • FPD: Q3 2015  
• LPCD: Q3 2016  
• Estimated completion: 2017 |
| **Phase III** | **NEPTUNE** | NSCLC 1L | N = 800 | • Arm 1: Durvalumab + tremelimumab  
• Arm 2: Standard of care | • OS  
• Safety | • FPD: Q4 2015  
• LPCD: 2017  
• Estimated completion: 2018 |
| **Phase III** | **EAGLE** | SCCHN 2L | N = 720 | • Arm 1: Durvalumab + tremelimumab  
• Arm 2: Durvalumab  
• Arm 3: Standard of care | • OS  
• PFS  
• Safety | • FPD: Q4 2015  
• LPCD: 2017  
• Estimated completion: 2018 |
| **Phase III** | **KESTREL** NCT02551159 | SCCHN 1L | N = 628 | • Arm 1: Durvalumab  
• Arm 2: Durvalumab + tremelimumab  
• Arm 3: Standard of care | • PFS  
• OS  
• Safety | • FPD: Q4 2015  
• LPCD: 2017  
• Estimated completion: 2018 |
| **Phase III** | **DANUBE** NCT02516241 | Bladder 1L cis eligible and ineligible | N = 525 | • Arm 1: Durvalumab + tremelimumab  
• Arm 2: Durvalumab  
• Arm 3: Standard of care | • PFS  
• OS  
• Safety | • FPD: Q4 2015  
• LPCD: 2017  
• Estimated completion: 2018 |
### 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**                   | SCCHN 2L PD-L1 negative                                 | N = 240            | • Arm 1: Durvalumab  
• Arm 2: Tremelimumab  
• Arm 3: Tremelimumab + durvalumab                                       | • ORR                                           | • FPD: Q2 2015  
• LPCD: Q2 2016  
• Estimated completion: 2017 |
| NCT02319044                           |                                                         |                    |                                                                        | • Safety                                        |                                                 |
| **Phase II ALPS**                     | Metastatic pancreatic ductal carcinoma 2L               | N = 130            | • Arm 1: Durvalumab + tremelimumab  
• Arm 2: Durvalumab                                                      | • Safety                                        | • FPD: Q4 2015  
• LPCD: 2017  
• Estimated completion: 2018 |
| NCT02558894                           |                                                         |                    |                                                                        | • Objective Response rate  
• Pharmacokinetics                      |                                                 |
| **Phase II**                          | Urothelial bladder cancer Triple-negative breast cancer Pancreatic ductal-adneocarcinoma | N=76               | • Arm 1 Tremelimumab in urothelial bladder cancer  
• Arm 2 Tremelimumab/triple-negative breast cancer  
• Arm 3 Tremelimumab pancreatic ductal-adneocarcinoma | • Safety                                        | • FPD: Q1 2016  
• Estimated completion: 2018 |
| NCT02527434                           |                                                         |                    |                                                                        | • Objective Response rate  
• Duration of Response                   |                                                 |
| **Phase I combination in advanced solid tumours in Japanese patients** | Solid tumours (treme Phase I)                           | N = 22             | • Tremelimumab + durvalumab  
• Dose escalation trial  
• Tremelimumab Q4W/Q12W 3-10mg/kg  
• Tremelimumab Q4W/Q12W X mg/kg + durvalumab Q4W X mg/kg | • Safety                                        | • FPD: Q2 2014  
• LPCD: Q2 2015  
• Estimated completion: H2 2016 |
| NCT02141347                           |                                                         |                    |                                                                        | • Optimal biologic dose                       |                                                 |
| **Phase 1 Combination in advanced solid tumours** | 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 (SFU) + leucovorin (calcium folinate/folinic acid) | • Safety                                        | • FPD: Q1 2016  
• LPCD: 2018  
• Estimated Completion: 2018 |
| NCT02658214                           |                                                         |                    |                                                                        |                                                 |
## 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 NSCLC patients | N = 1,100 | Arm 1: Durvalumab mg/kg IV Q4W x 12 mos  
Arm 2: Placebo  
Global trial | DFS  
OS | FPD: Q1 2015  
Estimated completion: 2020 |
| ADJUVANT  
NCT02273375  
Partnered with NCIC CTG | IB (≥4cm) – IIA resected NSCLC (incl. EGFR/ALK pos) | | | | |
| **Phase III** | Unresectable Stage III NSCLC patients following platinum-based concurrent chemoradiation therapy | N = 702 | Arm 1: Durvalumab IV Q2W  
Arm 2: placebo  
Global trial | PFS  
OS | FPD: Q2 2014  
LPCD: Q2 2016  
Estimated completion: 2017 |
| PACIFIC  
NCT02125461 | | | | | |
| **Phase III** | Stage IV squamous NSCLC patients  
Biomarker-targeted 2L therapy | N = 140 ; 100 Durvalumab treated (4,736 substudy only); Umbrella trial with 5 arms based on biomarker expression  
Substudy A: Durvalumab (non-match for other biomarker driven substudies) IVQ2W single arm durvalumab PhII only  
Substudy B: PI3K inhibitor vs. docetaxel  
Substudy C: CDK4/6 inhibitor vs. docetaxel  
Substudy D: AZD4547 (FGFR inhibitor) vs. docetaxel  
Substudy E: C-MET/HGFR Inhibitor + erlotinib vs. Erlotinib (Substudy is closed) | Arm 1: Durvalumab IV Q2W  
Arm 2: placebo  
Global trial | 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 |
| Lung Master Protocol  
NCT02154490  
Partnered with NCI, FNIH, and SWOG | | | | | |
| **Phase II** | Stage IIIB-IV NSCLC patients  
PD-L1+ve patients 3L | N = 293 | Arm 1: Durvalumab IV Q2W (EGFR/ALK WT)  
Arm 2: Durvalumab IV Q2W (EGFR/ALK M+)  
Arm 3: Durvalumab IV Q2W (EGFR/ALK WT) (90% PD-L1 - expression)  
Global trial – 18 countries | Complete Response Rate  
ORR, Disease Control Rate | FPD: Q3 2014  
LPCD: Q2 2016  
Estimated completion: H2 2016 |
| ATLANTIC  
NCT02087423 | | | | | |
| **Phase I/II** | Stage IIIb-IV NSCLC patients  
3L | N = 72 | Arm 1: Iressa initially then switch to durvalumab IVQ2W  
Arm 2: AZD9291 then switch to durvalumab  
Arm 3: selumetinib + docetaxel then switch to durvalumab  
Arm 4: tremelimumab then switch to durvalumab | Objective Response Rate  
Secondary endpoints include duration of response, PFS and OS | FPD: Q3 2014  
LPCD: Q2 2016  
Estimated completion: H2 2016 |
| Sequencing Trial  
NCT02179671 | | | | | |
# Cediranib (VEGF receptor inhibitor)

## Ovarian cancer

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
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<th>Design</th>
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</tr>
</thead>
</table>
| Phase III ICON 6 NCT00532194 | Patients with platinum-sensitive relapsed ovarian cancer | N = 486 | • Arm 1: Placebo  
• Arm 2: concurrent cediranib  
• Arm 3: concurrent and maintenance cediranib | • PFS | • FPD: Q2 2007  
• Completed |
Selumetinib (AZD6244) (MEK-inhibitor)

**Solid tumours**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III</strong> SELECT-1</td>
<td>2L KRASm positive NSCLC</td>
<td>N = 500</td>
<td>• Arm 1: Selumetinib 75mg BiD + docetaxel 75mg/m² IV on day 1 of each 21 day cycle&lt;br&gt;• Arm 2: Placebo BiD + docetaxel 75mg/m² IV on day 1 of each 21 day cycle&lt;br&gt;Global trial – 26 countries</td>
<td>• PFS&lt;br&gt;• OS is a secondary endpoint</td>
<td>• FPD: Q4 2013&lt;br&gt;• LPCD: Q1 2016&lt;br&gt;• Estimated top-line results: H2 2016</td>
</tr>
</tbody>
</table>

| Phase III ASTRA | Differentiated thyroid cancer | N = 304 | • Arm 1: Selumetinib 75mg BiD 5 weeks duration + RAI 100mCi<br>• Arm 2: Placebo BiD 5 weeks duration + RAI 100mCi<br>Global trial – eight countries<br>ªSingle dose of 100mCi ¹³¹I administered following 4 weeks of selumetinib (or placebo) | • Complete remission (CR) rate at 18 months post-RAI<br>• Clinical remission rate at 18 months post RAI (per SoC) | • FPD: Q3 2013<br>• LPCD: Q1 2016<br>• Estimated top-line results: 2017 |

| Phase II SELECT-2 | 2L KRASm negative NSCLC | N = 225 | • Arm 1: Selumetinib 75mg BiD + docetaxel 75mg/m² IV on day 1 of each 21 day cycle<br>• Arm 2: Selumetinib 75mg BiD + docetaxel 60mg/m² IV on day 1 of each 21 day cycle<br>• Arm 3: Placebo BiD + docetaxel 75mg/m² IV on day 1 of each 21 day cycle<br>Global trial – seven countries | • PFS<br>• OS is a secondary endpoint | • FPD: Q1 2013<br>• LPCD: Q4 2015<br>• Top-line results: Q2 2016 |

| Phase II | Pediatric Neurofibromatosis type 1 | N = minimum of 50 symptomatic points | • Single Arm: Selumetinib 25mg/m² BID with 2 strata:<br>• Stratum 1: PN related morbidity present at enrolment<br>• Stratum 2: No PN related morbidity present at enrolment | • Complete partial and complete response rate measured by volumetric MRI;<br>• Duration of response and functional outcomes/QoL | • FPD: Q3 2015<br>• LPCD: H2 2016<br>• Estimated top-line results: 2017 |

| Phase I | Advanced solid tumours | N = 40 | • Dose escalation trial: Starting dose Selumetinib 50mg bd 1 week on/1 week off - durvalumab 20mg/kg Q4 – after 7 days of selumetinib dosing<br>Note: No escalation in durvalumab dose; Selumetinib escalation with 25mg bd increment / dose cohort | • Safety and tolerability<br>• PK of Selumetinib and durvalumab and preliminary anti-tumour activity | • FPD: Q1 2016<br>• LPCD: 2017<br>• Estimated top-line results: 2017 |
## Acalabrutinib (ACP-196)
### Haematological malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
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<th>Endpoint(s)</th>
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</tr>
</thead>
</table>
| Phase III ACE-CL-006 ELEVATE-RR NCT02477696 | Relapsed/refractory CLL, high risk | N = 500 | • Arm A: Acalabrutinib  
• Arm B: Ibrutinib | PFS  
Secondary endpoints: comparison of incidence of infections, RTIs and atrial fibrillation, OS | • FPD: Q4 2015  
• Estimated completion: 2018 |
| Phase III ACE-CL-007 ELEVATE-TN NCT02475681 | Previously untreated CLL | N = 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 |
| Phase II ACE-CL-208 NCT02717611 | Relapsed/ refractory CLL, intolerant to ibrutinib | N = 80 | Acalabrutinib monotherapy | ORR at 36 cycles | • FPD: Q1 2016  
• Estimated completion: 2020 |
| Phase II 15-H-0016 NCT02337629 | Relapsed/refractory and treatment naive/del17p CLL/SLL | N = 48 | Acalabrutinib monotherapy  
• Arm A: Lymph node biopsy  
• Arm B: Bone marrow biopsy | Safety | • FPD: Q1 2015  
• Estimated completion: H2 2017 |
| Phase II ACE-LY-004 NCT02213928 | Relapsed/refractory Mantle Cell Lymphoma | N = 124 | Acalabrutinib monotherapy | ORR | • FPD: Q1 2015  
• LPCD: Q1 2016  
• Estimated completion: H2 2016 |
| Phase III ACE-CL-001 NCT02029443 | CLL/SLL/RT | N = 307 | Acalabrutinib monotherapy  
Dose escalation and expansion | Safety, PK, PD  
Secondary endpoints: ORR, DOR, and PFS | • FPD: Q1 2014  
• LPCD: Q2 2016  
• Estimated completion: 2019 |
| Phase III ACE-LY-001 NCT02328014 | B-Cell Malignancies | N = 126 | Dose escalation and expansion study of the combination of acalabrutinib and ACP-319 (PI3K inhibitor) | Safety  
ORR | • FPD: Q1 2015  
• Estimated completion: H2 2017 |
| Phase III ACE-LY-005 NCT02362035 | Hematological Malignancies | N = 324 | Acalabrutinib + pembrolizumab | 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>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase I/II</strong>&lt;br&gt;Ace-WM-001&lt;br&gt;NCT02180724</td>
<td>Waldenstrom Microglobulinemia&lt;br&gt;N = 106</td>
<td>Acalabrutinib monotherapy</td>
<td>ORR</td>
<td>• FPD: Q3 2014&lt;br&gt;• LPCD: Q4 2015&lt;br&gt;• Estimated completion: H2 2016</td>
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</tr>
<tr>
<td><strong>Phase Ib</strong>&lt;br&gt;Ace-LY-002&lt;br&gt;NCT02112526</td>
<td>Relapsed/refractory de novo ABC DLBCL&lt;br&gt;N = 21</td>
<td>Acalabrutinib monotherapy</td>
<td>Safety</td>
<td>• FPD: Q3 2014&lt;br&gt;• LPCD: Q2 2016&lt;br&gt;• Estimated completion: H1 2017</td>
<td></td>
</tr>
<tr>
<td><strong>Phase Ib</strong>&lt;br&gt;Ace-LY-106&lt;br&gt;NCT02717624</td>
<td>Mantle Cell Lymphoma&lt;br&gt;N = 48</td>
<td>Acalabrutinib in combination with bendamustine and rituximab&lt;br&gt;• Arm A: Treatment naive&lt;br&gt;• Arm B: Relapsed/refractory</td>
<td>Safety</td>
<td>• FPD: Q2 2016&lt;br&gt;• Estimated completion: 2021</td>
<td></td>
</tr>
<tr>
<td><strong>Phase Ib</strong>&lt;br&gt;Ace-MY-001&lt;br&gt;NCT02211014</td>
<td>Relapsed/refractory Multiple Myeloma&lt;br&gt;N = 40</td>
<td>Arm A: Acalabrutinib&lt;br&gt;Arm B: Acalabrutinib + dexamethasone</td>
<td>Safety</td>
<td>• FPD: Q1 2015&lt;br&gt;• Estimated completion: H1 2017</td>
<td></td>
</tr>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;Ace-LY-003&lt;br&gt;NCT02180711</td>
<td>Relapsed/refractory Follicular Lymphoma&lt;br&gt;N = 38</td>
<td>Arm A: Acalabrutinib&lt;br&gt;Arm B: Acalabrutinib + rituximab</td>
<td>Safety</td>
<td>• FPD: Q1 2015&lt;br&gt;• LPCD: Q2 2016&lt;br&gt;• Estimated completion: 2018</td>
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<tr>
<td><strong>Phase I</strong>&lt;br&gt;Ace-CL-002&lt;br&gt;NCT02157324</td>
<td>Relapsed/refractory CLL&lt;br&gt;N = 12</td>
<td>Acalabrutinib in combination with ACP-319&lt;br&gt;Dose escalation</td>
<td>Safety, PK, PD</td>
<td>• FPD: Q3 2014&lt;br&gt;• LPCD: Q3 2015&lt;br&gt;• Estimated completion: 2018</td>
<td></td>
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<tr>
<td><strong>Phase I</strong>&lt;br&gt;Ace-CL-003&lt;br&gt;NCT02296918</td>
<td>CLL/PLL&lt;br&gt;N = 45</td>
<td>Acalabrutinib + obinutuzumab&lt;br&gt;• Arm A: Relapsed/refractory&lt;br&gt;• Arm B: Treatment naive</td>
<td>Safety ORR</td>
<td>• FPD: Q1 2015&lt;br&gt;• LPCD: Q1 2016&lt;br&gt;• Estimated completion: 2018</td>
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</tbody>
</table>
# Acalabrutinib (ACP-196)

## Solid Tumours

<table>
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<tr>
<th>Trial phase</th>
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<th>Number of patients</th>
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<th>Endpoint(s)</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II ACE-ST-006 NCT02454179 | ≥ 2L advanced or metastatic head and neck squamous cell carcinoma | N = 78 | • Arm A: Pembrolizumab  
• Arm B: Acalabrutinib+ pembrolizumab | ORR | • FPD: Q2 2015  
• LPCD: Q2 2016  
• Estimated completion: Q2 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  
• LPCD Q2 2016  
• Estimated completion: H1 2017 |
| Phase II ACE-ST-208 NCT02533444 | Recurrent ovarian cancer | N = 78 | • Arm A: Acalabrutinib  
• Arm B: Acalabrutinib+ pembrolizumab | ORR | • FPD: Q4 2015  
• LPCD Q2 2016  
• Estimated completion: H2 2017 |
| Phase II ACE-ST-004 NCT02570711 | 1L metastatic pancreatic cancer | N = 3 | • Arm A: Acalabrutinib+ Nab-Paclitaxel+ Gemcitabine  
• Arm B: Nab-Paclitaxel+ Gemcitabine | ORR | • FPD: Q4 2015  
• LPCD Q1 2016  
• Trial terminated |
| Phase II ACE-ST-003 NCT02362048 | ≥ 2L advanced or metastatic pancreatic cancer | N = 77 | • Arm A: Acalabrutinib  
• Arm B: Acalabrutinib+ pembrolizumab | Safety | • FPD: Q2 2015  
• LPCD Q1 2016  
• Estimated completion: H1 2017 |
| Phase II ACE-ST-005 NCT02351739 | Platinum-resistant urothelial bladder cancer | N = 78 | • Arm A: Pembrolizumab  
• Arm B: Acalabrutinib+ pembrolizumab | ORR | • FPD: Q2 2015  
• LPCD Q1 2016  
• Estimated completion: H1 2017 |
| Phase Ib/II ACE-STA-209 NCT02586857 | ≥ 2L glioblastoma multiforme | N = 72 | • Arm A: Acalabrutinib 200mg BID  
• Arm B: Acalabrutinib 400mg QD | Safety ORR | • FPD: Q1 2016  
• Estimated completion: 2018 |
# Moxetumomab pasudotox (CD22 mAb)

## Haematological malignancies

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Endpoints</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Phase III</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</td>
<td>FPD: Q2 2013</td>
</tr>
<tr>
<td>PLAIT NCT01829711</td>
<td></td>
<td></td>
<td></td>
<td>Efficacy: CR rate, ORR, Duration of CR and ORR, time to response (TTR), PFS</td>
<td>LPCD: H2 2016</td>
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<tr>
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<td></td>
<td>Safety and tolerability</td>
<td>Estimated top-line results: 2017</td>
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<tr>
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<td></td>
<td>PK and immunogenicity</td>
<td></td>
</tr>
<tr>
<td>Phase I</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</td>
</tr>
<tr>
<td>NCT00586924</td>
<td></td>
<td></td>
<td></td>
<td>LPCD: Q1 2014</td>
<td>Top-line results: Q2 2015 (completed)</td>
</tr>
</tbody>
</table>
# AZD3293 (BACE inhibitor)

## Alzheimer’s disease

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase III AMARANTH NCT02245737 | Early Alzheimer's disease patients | N = 2,202 | • Arm 1: AZD3293 20mg once daily  
• Arm 2: AZD3293 50mg once daily  
• Arm 3: Placebo once daily  
24-month treatment duration  
Global trial – 14 countries | • Changes in cognitive (ADAS-Cog 13) and functional (ADCS-ADL) scales  
• Changes in composite scales (CDR-SB)  
• Changes in biomarkers and imaging assays  
• Safety and tolerability | • FPD: Q4 2014  
• LPCD: 2017  
• Estimated top-line results: 2019 |
## Verinurad (RDEA3170 - SURI, URAT1 inhibitor)
### Gout and hyperuricemia development programme

<table>
<thead>
<tr>
<th>Trial phase</th>
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</tr>
</thead>
</table>
| Phase II    | Combination therapy trial with febuxostat in subjects with gout | N = 60 | • Arm A: Verinurad 2.5mg QD  
• Arm B: Verinurad 5.0mg QD  
• Arm C: Verinurad 10mg QD  
• Arm D: Verinurad 15mg QD  
• Arm E: Sequential doses of verinurad 10, 15 and 20mg QD in combination with 40mg QD febuxostat  
*Arms A-D include combination with 40mg QD febuxostat for 7 days followed by combination with 80mg QD febuxostat for 7 days | • To assess the PK and PD profiles of verinurad administered with febuxostat | FPD: Q4 2014  
LPCD: Q2 2015  
Complete |
| Phase II    | Combination study with febuxostat for treating gout or asymptomatic hyperuricemia in Japanese patients | N = 92 | • Arm A: Verinurad 2.5mg QD + 10mg or 20mg QD febuxostat  
• Arm B: Verinurad 5.0mg QD + 10mg or 20mg QD febuxostat  
• Arm C: Verinurad 5.0mg QD + 20mg or 40mg QD febuxostat  
• Arm D: Verinurad 10mg QD + 20mg or 40mg QD febuxostat  
• Arm E: Benz bromarone 50mg QD | • To assess the PD, PK and safety profiles of verinurad administered with febuxostat | FPD: Q4 2014  
LPCD: Q2 2015  
Complete |
| Phase II    | Combination therapy trial with allopurinol in subjects with gout | N = 40 | • Arm A: Placebo  
• Arm B: Verinurad 2.5mg QD  
• Arm C: Verinurad 5.0mg QD  
• Arm D: Verinurad 7.5mg QD  
• Arm E: Verinurad 10mg QD  
• Arm F: Verinurad 15mg QD  
• Arm G: Verinurad 20mg QD  
*All arms include combination with 300mg QD allopurinol. Placebo group also includes combination with 300mg BID allopurinol or 600mg QD allopurinol | • To assess the PK and PD profiles of verinurad administered with allopurinol | FPD: Q3 2015  
LPCD: Q4 2015  
Estimated completion: H2 2016 |
| Phase I     | Pharmacokinetic and Pharmacodynamic trial in healthy adult male subjects | N = 40 | • Part 1: Single doses of verinurad at 4.5mg, 6.0mg, or 12mg  
• Part 2: Multiple doses of verinurad at 12mg QD for 7 days  
• Part 3: Food effect trial with single doses of verinurad at 6.0mg | • To assess the PK, PD and food effect profiles of verinurad | FPD: Q4 2015  
LPCD: Q4 2015  
Estimated completion: H2 2016 |
<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Endpoints</th>
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</tr>
</thead>
<tbody>
<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 cross-over, multi-centre trial to assess efficacy and safety of three dose levels of AZD7594, given once daily by inhalation, in patients with mild to moderate asthma</td>
<td>• Forced expiratory volume in one second (FEV1)</td>
<td>• FPD: Q3 2015  • Completed</td>
</tr>
<tr>
<td>NCT02479412</td>
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<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>NCT01636024</td>
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</tr>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>N = 24</td>
<td>An open label, partially randomised, four-period trial in healthy male subjects to investigate the bioavailability and pharmacokinetics of a single dose of AZD7594 when administered 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  • Completed</td>
</tr>
<tr>
<td>NCT02648438</td>
<td></td>
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<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 trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses of AZD7594 given once daily as inhaled formulation in healthy Japanese men</td>
<td>• Safety and tolerability</td>
<td>• FPD: Q1 2016  • Completed</td>
</tr>
<tr>
<td>NCT02645253</td>
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</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>
<tbody>
<tr>
<td>Phase IIa NCT02238483</td>
<td>COPD</td>
<td>N = 212</td>
<td>• Arm 1: AZD7624, 1.0mg&lt;br&gt;• Arm 2: placebo&lt;br&gt;Inhaled (nebulised) administration&lt;br&gt;Trial conducted in US, EU, South Africa &amp; South America</td>
<td>• Effect on rate of exacerbations and lung function compared to placebo</td>
<td>FPD: Q4 2014&lt;br&gt;Completed</td>
</tr>
<tr>
<td>Phase Ib LPS NCT01937338</td>
<td>Healthy subjects</td>
<td>N = 30</td>
<td>• 2-way cross-over RCT&lt;br&gt;• Single administration of 1200μg of AZD7624 or placebo at 0.5 hours prior to lipopolysaccharide (LPS) challenge.&lt;br&gt;Inhaled (nebulised) administration&lt;br&gt;Trial conducted in the UK</td>
<td>• Effect on neutrophils in induced sputum after oral inhalation of LPS; compared to placebo</td>
<td>FSD: Q4 2013&lt;br&gt;Completed</td>
</tr>
<tr>
<td>Phase I NCT01754844</td>
<td>Healthy subjects</td>
<td>N = 48</td>
<td>SAD&lt;br&gt;• Five different dose levels investigated vs placebo&lt;br&gt;Inhaled (nebulised) administration&lt;br&gt;Trial conducted in the UK</td>
<td>• Safety and tolerability following inhaled administration with single ascending dose</td>
<td>FSD: Q1 2013&lt;br&gt;Completed</td>
</tr>
<tr>
<td>Phase I NCT01817855</td>
<td>Healthy subjects and COPD</td>
<td>N = 47</td>
<td>MAD&lt;br&gt;• Different dose levels investigated vs placebo in healthy volunteers and patients with COPD&lt;br&gt;Inhaled (nebulised) administration&lt;br&gt;Trial conducted in the UK</td>
<td>• Safety and tolerability in healthy subjects and patients with COPD following administration of multiple ascending inhaled doses</td>
<td>FSD: Q3 2013&lt;br&gt;Completed</td>
</tr>
</tbody>
</table>
## 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) • Five different dose levels investigated vs placebo • oral administration</td>
<td>• Safety and tolerability and PK following oral administration with single ascending dose • Preliminary assessment of the effect of food on the single dose PK parameters of AZD7986</td>
<td>• FPD: Q4 2014 • Completed</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Part 2 (MAD) • Three different dose levels investigated vs placebo in healthy volunteers • oral administration</td>
<td>• Safety and tolerability &amp; PK in healthy subjects following administration of multiple ascending oral doses • NE activity</td>
<td>• FPD: Q1 2016 • Completed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Trial conducted in the UK</td>
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</tr>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>N = 15</td>
<td>A phase 1, non-randomized, fixed sequence, 3-period, drug-drug interaction trial to assess the pharmacokinetics (PK) of AZD7986 in healthy subjects when administered alone and in combination with multiple doses of verapamil and itraconazole or diltiazem.</td>
<td>• Effect of verapamil and the effect of itraconazole/diltiazem on the pharmacokinetics (PK) of AZD7986 • Safety and tolerability of AZD7986</td>
<td>• FD: Q1 2016 • Completed</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>
<tbody>
<tr>
<td>Phase I</td>
<td>NCT02573155</td>
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<tr>
<td></td>
<td>Part 1: Mild Asthmatic</td>
<td>N (Part 1) = 16</td>
<td>Part 1</td>
<td>To assess the safety and tolerability of single doses of AZD8871 administered by inhalation to mild persistent asthmatic male subjects</td>
<td>Part 1 Endpoints:</td>
</tr>
<tr>
<td></td>
<td>Part 2: Moderate to severe COPD</td>
<td>N (Part 2) = 40</td>
<td></td>
<td>To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8871 in mild persistent asthmatic male subjects</td>
<td>• FPD: Q4 2015</td>
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<td></td>
<td>• LPCD: Q4 2015</td>
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<td>Part 1</td>
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<td>Part 2 Endpoints:</td>
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<tr>
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<td></td>
<td>• To assess the safety and tolerability of single doses of AZD8871 administered by inhalation to moderate to severe COPD subjects</td>
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<tr>
<td></td>
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<td>• To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8871 in moderate to severe COPD subjects</td>
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<td>• FPD: Q2 2016</td>
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<td>• LPCD: H2 2016</td>
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<td>Estimated Topline Results: H2 2016</td>
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<td>Estimated Completion: H1 2017</td>
</tr>
<tr>
<td>Phase I</td>
<td>NCT02814656</td>
<td>N = 24</td>
<td>MAD study with 3 planned dose levels - 300μg, 600/900μg, up to 1800μg and placebo</td>
<td>Primary Endpoint:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Healthy Volunteers</td>
<td></td>
<td></td>
<td>• The primary objective is to investigate the safety and tolerability of AZD8871 at steady state</td>
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<td></td>
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<td>Secondary Endpoint:</td>
<td></td>
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<tr>
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<td>• To characterize the PK of AZD8871 and its metabolites LAS191861 and LAS34850 after multiple doses of AZD8871 and assess the time required to reach steady state, the degree of accumulation and the time dependency</td>
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<td>• FPD: H2 2016</td>
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<td>• LPCD: H2 2016</td>
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<td>Estimated Topline Results: H2 2016</td>
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<td>Estimated Completion: H1 2017</td>
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</tbody>
</table>
## 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 INEXAS | Asthma | N = 220 | • Arm 1: 24μg (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 |
# AZD9567 (oSGRM)
## Rheumatoid Arthritis

<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 = 72             | SAD trial with 6 dose levels - 2μg, 10μg, 40μg, 100μg, 200μg, and up to 400μg | • 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 (all capitals!) | • FPD: Q4 2015  
• LPCD: Q2 2016  
Estimated Topline Results: H2 2016  
Estimated Completion: H2 2016 |
| NCT02512575 |                    |                    | Global trial – one country | | |
| Phase I     | Healthy Volunteers | N = 36             | MAD trial with 4 dose levels – 10mg, 20mg, 40mg, 80mg and Prednisolone 20 mg | Primary Endpoint:  
• To assess the safety and tolerability of AZD9567 following multiple oral administration of ascending doses.  
Secondary Endpoints:  
• To characterize the pharmacokinetics of AZD9567 following multiple oral ascending doses.  
• To characterize the pharmacodynamics of AZD9567 assessed as effect on glucose homeostasis through OGTT (oral glucose tolerance test) in comparison with prednisolone 20mg | • FPD: Q2 2016  
• LPCD: H2 2016  
Estimated Topline results: H1 2017  
Estimated Completion: H1 2017 |
| NCT02760316 |                    |                    | Global trial – two countries | | |
# 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>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy subjects</td>
<td>N = up to 48</td>
<td>SAD trial (one study site in US)</td>
<td>Safety and tolerability, PK parameters</td>
<td>FPD: Q4 2015, LPCD: H2 2016, Estimated completion: 2017</td>
</tr>
<tr>
<td>NCT02612662</td>
<td></td>
<td></td>
<td>• Up to 6 different dose levels investigated vs. placebo, Sub-cutaneous injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I/IIa</td>
<td>Type-2 Diabetic patients with non-alcoholic fatty liver disease</td>
<td>N = up to 51</td>
<td>MAD trial (one study site in US)</td>
<td>Safety and tolerability, Glucose infusion rate at hyperinsulinemic clamp, Reduction in liver fat content (%) per MRI, 24 hour glucose area under the curve, PK parameters</td>
<td>FPD: H2 2016, LPCD: H1 2017, Estimated completion: 2017</td>
</tr>
<tr>
<td>NCT02826525</td>
<td></td>
<td></td>
<td>• Up to 3 different dose levels investigated vs. placebo, Sub-cutaneous injection</td>
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</tr>
</tbody>
</table>
## AZD4831

### Cardiovascular 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 = 96</td>
<td>SMAD trial (one study site in Germany) SAD • Planned to investigate 6 different dose levels vs. placebo but up to 10 cohort may be used MAD • The planned number of cohorts is three but up to five cohorts may be included</td>
<td>• Safety and tolerability • PK parameters</td>
<td>• FPD: H2 2016 • LPCD: H1 2017 • Estimated completion: H2 2017</td>
</tr>
</tbody>
</table>

**NCT02712372**
# AZD5718

## Cardiovascular 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 = 96</td>
<td>SMAD trial (one study site in UK) SAD • Planned to investigate 8 different dose levels vs. placebo but up to 11 cohort may be used • Amorphous and crystalline form of AZD5718 will be investigated • Oral administration MAD • The planned number of cohorts is four but up to six cohorts may be included • Once or twice daily oral administration of AZD5718</td>
<td>• Safety and tolerability • PK parameters • Pharmacodynamic analysis by ex-vivo stimulation of LTB4 production using calcium ionophore • Pharmacodynamics of AZD5718 after single single ascending doses and multiple ascending doses • To evaluate the relative bioavailability between the amorphous and crystalline form of AZD5718</td>
<td>FPD: Q1 2016 • LPCD: H2 2016 • Estimated completion: H2 2016</td>
</tr>
<tr>
<td>NCT02632526</td>
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</table>

**Note:**
- **SMAD trial (one study site in UK)**
- **SAD**
- **MAD**
- **NCT02632526**
## 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     | Solid tumours      | N = 130            | • Arm 1: AZD0156 + Lynparza  
• Arm 2: AZD0156 + irinotecan | • Safety, tolerability, pharmacokinetics and efficacy | • FPD: Q4 2015  
• Estimated completion: 2018 |

Trial conducted in North America, Europe and South Korea.

---

**Patient population**: Solid tumours

**Number of patients**: N = 130

**Design**:  
- Arm 1: AZD0156 + Lynparza
- Arm 2: AZD0156 + irinotecan

**Endpoints**:  
- Safety, tolerability, pharmacokinetics and efficacy

**Status**:  
- FPD: Q4 2015
- Estimated completion: 2018

---

**Trial phase**: Phase I

**Patient population**: Solid tumours

**Number of patients**: N = 130

**Design**:  
- Arm 1: AZD0156 + Lynparza
- Arm 2: AZD0156 + irinotecan

**Endpoints**:  
- Safety, tolerability, pharmacokinetics and efficacy

**Status**:  
- 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 NCT01357161 | 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 NCT02272790 | PR ovarian cancer | N = 70 | • Arm C: Carboplatin + AZD1775  
Global trial | • Overall Response Rate (ORR)  
• Secondary endpoints: Duration of Response (DOR), PFS, OS, Disease Control Rate, safety and tolerability | • FPD: Q1 2015  
• LPCD: H2 2016  
• Estimated completion: H2 2016 |
| Phase III NCT02482311 | Advanced solid tumours | N = 152 | • Monotherapy  
Safety Run-in (part A, N=12); solid tumours  
Expansions into specific tumour types, inc ovarian cancer  
(BRCAn PARP failures and BRCAw 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: 2019  
• Estimated completion: 2019 |
| Phase I NCT02610075 | Advanced solid tumours | N = 18 | • Monotherapy  
Dose escalation trial to determine MTD  
Conducted in US | • Safety and tolerability | • FPD: Q4 2015  
• LPCD: H1 2017  
• Estimated completion: H1 2017 |
| Phase I NCT02511795 | Advanced solid tumours | N = 36 | • Dose escalation trial (AZD1775 + Lynparza)  
Conducted in US | • Safety and tolerability | • FPD: Q3 2015  
• LPCD: H2 2016  
• Estimated completion: H1 2017 |
| Phase I NCT02617277 | Advanced solid tumours | N = 18 | • Dose escalation trial (AZD1775 + durvalumab)  
Conducted in US | • Safety and tolerability | • FPD: Q4 2015  
• LPCD: H1 2017  
• Estimated completion: 2018 |
| Phase I NCT02341456 | 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 |
<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 | STORK NCT02403895 | Relapsed or refractory squamous NSCLC (at least one prior therapy) | N = 40 | Open label | • 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 |
|             |                    |                   | 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 |
| Phase III | PASTOR NCT02599714 | 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) |
|             |                    |                   | 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) |

**Vistusertib (AZD2014) (TORC 1/2)**

**Breast and squamous Non-Small Cell Lung Cancer (NSCLC)**
# 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 NCT02579226 | 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 |
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: H1 2017 |
# AZD4547 (FGFR)

## Solid tumours

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<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  | 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))  
  Conducted in eight countries in Europe | • Part A: MTD of AZD4547 in combination with 25mg exemestane in three schedules of AZD4547  
• Part B: Interim analysis: Tumour size analysis on 30 FGFR amplified patients  
• Part B Final analysis: PFS | • FPD: Q4 2010  
• LPCD: Q1 2014  
• Completed: Q3 2014 |
| Phase II  | 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))  
Conducted in 16 countries across Europe and Asia | • PFS  
• Key Secondary: OS/Tumour size | • FPD: Q4 2011  
• LPCD: Q2 2013  
• Recruitment closed after interim analysis: Q2 2013  
• Completed: Q1 2015 |
| Phase I  | 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. eight patients)  
Conducted in Japan | • Part A: MTD and Recommended dose for Parts B and C  
• Part B: Safety and tolerability and preliminary anti-tumour activity | • FPD: Q4 2010  
• LPCD: Q4 2012  
• Completed: Q2 2013 |
| Phase I  | 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  
Conducted in seven countries across North America and Europe | • Part A: MTD and Recommended dose for Parts B and C  
• Part B and C: Safety and tolerability, PK and preliminary anti-tumour activity | • FPD: Q4 2009  
• LPCD: Q4 2013  
• Completed: Q1 2015 |
| Phase I  | 2L Muscle Invasive Metastatic Bladder Cancer in patients who have failed prior therapy | N = 110 | • Multi-drug biomarker-directed trial  
• Arm 1: AZD454  
• Arm 2: AZD4547 + durvalumab  
• Arm 3: Lynparza + durvalumab  
• Arm 4: AZD1775 + durvalumab  
• Arm 5: durvalumab  
Planned in North America and Europe | • Safety and tolerability of the combinations  
• PK and preliminary anti-tumour activity | • FPD Estimated: Q3 2016  
• Estimated completion: 2018 |
## AZD4635 (A2AR)

**Solid tumours and Non Small Cell Lung Cancer (NSCLC)**

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
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<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Phase 1a: patients with advanced solid tumours</td>
<td>N = 36 (estimated)</td>
<td>• Phase 1a: dose escalation to determine the Maximum Tolerated Dose (MTD) of AZD4635 given as monotherapy and in combination with durvalumab. When the combination MTD is determined, additional patients with advanced solid malignancies will be enrolled to a dose expansion cohort to explore further the safety, tolerability, pharmacokinetics (PK), and biological activity.</td>
<td>Primary Outcome Measure: Safety and tolerability</td>
<td>• FPD: Q2 2016</td>
</tr>
<tr>
<td></td>
<td>Phase 1b: patients with advanced NSCLC who have previously received anti-PD-1 therapy, but either failed to respond or stopped responding after an initial response</td>
<td>N = 15</td>
<td>• Phase 1b will consist of an additional expansion phase in NSCLC at the combination MTD or maximum feasible dose</td>
<td>Secondary Outcome Measures: • Pharmacokinetics of AZD4635 as monotherapy and combination with durvalumab • Preliminary assessment of anti-tumour activity</td>
<td>• Estimated completion: 2018</td>
</tr>
<tr>
<td>NCT02740985</td>
<td></td>
<td></td>
<td>Both parts conducted at sites in the US</td>
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</tbody>
</table>
# AZD5069 (CXCR2)

## Solid Tumors

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
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<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase Ib/II</td>
<td>Metastatic Pancreatic Ductal Carcinoma</td>
<td>N = 26</td>
<td>Dose escalation and expansion Arms: Durvalumab in combination with nab-paclitaxel and gemcitabine Durvalumab in combination with AZD5069</td>
<td>Safety/Efficacy trial</td>
<td>• FPD: Q1 2016 • LPCD: 2017 • Estimated completion: 2017</td>
</tr>
</tbody>
</table>

*clinicaltrials.gov being updated*
### 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>
</table>
| **Phase IIb** | ER+ breast cancer receiving 1st treatment with paclitaxel in the advanced setting | N = 100            | • Arm 1: AZD5363 + paclitaxel  
• Arm 2: AZD5363 placebo + paclitaxel  
Two strata (50 points per stratum): PIK3CA mutation positive vs Mutation not detected | • PFS  
• Response rate (ORR) & OS are secondary endpoints | • FPD: Q1 2014  
• Estimated primary completion: H2 2016  
• Estimated completion: 2017 |
| NCT01625266 | **Phase I**  
Breast and gynaecological cancers with PIK pathway mutation | N = 20 per arm (Parts C & D)  
N = 12-24 per arm (Parts E & F) | Monotherapy AZD5363 480mg BD 4 days on 3 days off  
• Part C arm 1: Breast with PIK3CA mutation  
• Part C arm 2: Gynaecological with PIK3CA mutation  
• Part D arm 1: Breast with AKT-1 mutation  
• Part D arm 2: Gynaecological with AKT-1 mutation  
• Part D arm 3: Other tumours with AKT-1 mutation  
AZD5363 400mg BD 4 days on 3 days off combined with 500mg fulvestrant (initially 12 patients per arm with option to expand to 24 patients in one or more arms)  
• Part E arm 1: ER+ Breast with AKT-1 mutation (prior Faslodex resistance)  
• Part E arm 2: ER+ Breast with AKT-1 mutation (first exposure to Faslodex)  
• Part F arm 1: ER+ Breast with PTEN mutation (prior Faslodex resistance)  
• Part F arm 2: ER+ Breast with PTEN mutation (first exposure to Faslodex) | • Safety and tolerability  
• Response Rate (ORR)  
• Clinical Benefit Rate at 24 weeks (CBR24) [Parts E & F only] | • FPD: Q3 2013  
• Estimated primary completion: H2 2017  
• Part C Arms 1 & 2 completed  
• Part D Arms 1 & 3 completed  
• Part D Arm 2 paused pending interim analysis  
• Part E Arms 1 & 2 ongoing  
[CBR24 data for 12 patients per arm estimated 2017]  
• Part F Arms 1 & 2 ongoing |
# 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>Phase II</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&lt;br&gt;LPCD: H1 2017&lt;br&gt;Estimated completion: 2017</td>
</tr>
<tr>
<td>NCT02127710</td>
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<tr>
<td>Phase I</td>
<td>Advanced cancer (all comers)</td>
<td>N ~50</td>
<td>Dose escalation trial Conducted in Australia</td>
<td>Safety and tolerability</td>
<td>FPD: Q1 2012&lt;br&gt;LPCD: Q3 2015&lt;br&gt;Estimated completion: H2 2016</td>
</tr>
<tr>
<td>NCT01773018</td>
<td>Partnered</td>
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<tr>
<td>Phase I</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&lt;br&gt;LPCD: H2 2016&lt;br&gt;Estimated completion: 2017</td>
</tr>
<tr>
<td>NCT01985555</td>
<td>Partnered</td>
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<tr>
<td>Phase I</td>
<td>Advanced gastric cancer (all comers)</td>
<td>N ~25</td>
<td>Dose escalation trial Conducted in China</td>
<td>Safety and tolerability</td>
<td>FPD: Q4 2014&lt;br&gt;LPCD: Q4 2015&lt;br&gt;Terminated</td>
</tr>
<tr>
<td>NCT02252913</td>
<td>Partnered</td>
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<tr>
<td>NCT02374645</td>
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# AZD6738 (ATR) Solid tumours

<table>
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<tr>
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</tr>
</thead>
</table>
| Phase I NCT02264678 | Solid tumours | N = 160 | • Arm 1: AZD6738 + carboplatin  
• Arm 2: AZD6738 dose escalation AZD6738 + Lynparza  
• 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 |
# AZD8186 (PI3Kb/d)
## Solid tumours

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
<th>Number of patients</th>
<th>Design</th>
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</tr>
</thead>
</table>
| Phase I | 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 anti-tumour activity (POM)  
• Part C: PK, safety, tolerability and recommended dose/ schedule of AZD8186 in combination with abiraterone. Preliminary assessment of anti-tumour activity of AZD8186 in combination with abiraterone.  
• 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>
| Phase Ib/II | Squamous Cell Carcinoma of the Head & Neck (SCCHN) | N = 147 | Dose Escalation advanced solid and haematological cancers  
- Arm A1: AZD9150/durvalumab  
- Arm A2: AZD5069/durvalumab  
Dose Expansion 2L SCCHN:  
- Arm B1: AZD9150  
- Arm B2: AZD5069  
- Arm B3: AZD9150/durvalumab  
LPCD: 2017  
Estimated completion: 2019 |
| Phase 1b/II | Diffuse Large B-cell Lymphoma | N = 186 | Dose escalation and expansion Arms:  
Experimental Arm: durvalumab monotherapy  
Experimental Arm: durvalumab and tremelimumab  
Experimental Arm: durvalumab and AZD9150 | Safety/Efficacy trial | FPD: Q2 2016  
LPCD: 2021  
Estimated completion: 2021 |

*clinicaltrials.gov* being updated
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                                                                 |
| Phase I     | Healthy subjects               | N ~ 14             | • This is a Phase I open label single centre trial to assess the pharmacokinetics and safety of different forms and formulations of AZD9496 in healthy subjects                                                                 | • Primary Outcome Measures: Pharmacokinetics for AZD9496 and its metabolites  
• Secondary Outcome Measures: Safety and tolerability                                                                 | • FPD: Q2 2016  
• Estimated completion: H2 2016                                                                 |
<table>
<thead>
<tr>
<th>Trial phase</th>
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</tr>
</thead>
</table>
| Phase II   | Complicated Intra-Abdominal Infections (cIAIs) | N = 40            | • Prospective open-label, multicentre trial to determine the pharmacokinetics (PK) and safety and tolerability of aztreonam-avibactam (ATM-AVI) for the treatment of complicated Intra-Abdominal Infections (cIAIs) in hospitalized adults  
Multi-centre trial in Germany, France, Spain | • Pharmacokinetics  
• Safety/tolerability  
• Treatment Outcomes (secondary) | • FPD: Q2 2016  
• LPCD: H1 2017  
• Completion: H2 2017 |
| NCT02655419|                                        |                    |                                                                        |                                                                           |                               |
**AZD3241 (MPO)**

**Multiple System Atrophy (MSA)**

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase II NCT01527695 | Parkinson’s disease patients | N = 24 | • Arm 1: AZD3241 600mg 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 300mg BID for 12 weeks  
• Arm 2: AZD3241 600mg 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 = 30 | • Arm 1: AZD3241 300mg BID for 12 weeks  
• Arm 2: AZD3241 600mg BID for 12 weeks  
• Arm 3: Placebo  
Randomisation 1:1:1 across arms  
Eight sites in US  
Nine sites in Europe | • Microglia activation represented by [11C]PBR28 binding  
• AEs, labs, vital signs, ECGs  
Secondary endpoints:  
• MSA symptoms measured by UMSARS and MSA QoL  
• 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>
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<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy volunteers</td>
<td>N = 40</td>
<td>• Randomised, double-blind, placebo-controlled&lt;br&gt;• Part 1 SAD 3 dosage-level cohorts&lt;br&gt;• Part 2 MAD 2 dosage-level cohorts&lt;br&gt;US only trial – one site</td>
<td>• Safety and tolerability&lt;br&gt;Additional endpoints:&lt;br&gt;• Pharmacokinetics&lt;br&gt;• Pharmacodynamics</td>
<td>• FPD: Q4 2014&lt;br&gt;• LPCD: Q3 2015&lt;br&gt;• Top-line results: Q2 2016</td>
</tr>
</tbody>
</table>
Early development - MedImmune
# MEDI5872 (B7RP-1 mAb)

## Systemic Lupus Erythematosus (SLE)

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Patient population</th>
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<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Phase IIIa  | Primary Sjögren's syndrome                               | N = 42             | • Arm 1: MEDI5872 210mg 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>
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</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Healthy volunteers</td>
<td>N = 32</td>
<td>• Arm 1: 30mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose</td>
<td>• Safety and tolerability</td>
<td>• FPD: Q1 2015</td>
</tr>
<tr>
<td>NCT02388347</td>
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<td>• Arm 2: 105mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose</td>
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<td>• LPCD: Q3 2015</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>• Arm 3: 300mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose</td>
<td></td>
<td>• Top-line results: Q1 2016</td>
</tr>
<tr>
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<td>• Arm 4: 600mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose</td>
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</tbody>
</table>
# MEDI9314 (IL-4Ra mAb)

## Atopic Dermatitis

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<tr>
<th>Trial phase</th>
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<th>Number of patients</th>
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<th>Status</th>
</tr>
</thead>
</table>
| Phase I NCT 02669667 | Healthy volunteers | N = 44 | • Arm 1: 45mg MEDI9314 (n = 4) or placebo (n = 2) as a single SC dose  
• Arm 2: 150mg MEDI9314 (n = 4) or placebo (n = 2) as a single SC dose  
• Arm 3: 300mg MEDI9314 (n = 6) or placebo (n = 2) as a single SC dose  
• Arm 4: MEDI9314 (n = 6) or placebo (n = 2) as a single IV dose  
• Arm 5: 300mg MEDI9314 (n = 6) or placebo (n = 2) as a single SC dose (Japanese subjects)  
• Arm 6: 450mg 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 |
# MEDI9929 (TSLP mAb)

## Asthma

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Number of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase II** | Adult subjects with inadequately controlled, severe asthma | N = 552 | • Arm 1: Placebo  
• Arm 2: Low dose MEDI9929 70mg SC  
• Arm 3: Medium dose MEDI9929 210mg SC  
• Arm 4: High dose MEDI9929 280mg SC | • Reduction in the annualised asthma exacerbation rate (AER) measured at week 52 | • FPD: Q2 2014  
• LPCD: Q4 2015  
• Estimated top-line results: H2 2016 |
| PATHWAY     | Partnered          |                    |       |           |        |
| NCT02054130 |                    |                    |       |           |        |

| Phase II | Adult subjects with moderate-to-severe atopic dermatitis | N = 100 | • Arm 1: Placebo  
• Arm 2: Dose of MEDI9929 SC | • 50% reduction from baseline in the eczema area and severity index measured at week 12 | • FPD: Q2 2015  
• LPCD: H2 2016  
• Estimated top-line results: H2 2016 |
| NCT02525094 | Partnered |                    |       |           |        |
### 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 | | | |
| Phase II    | Patients with moderate to severe Crohn’s disease | 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 |
| NCT02574637 | Partnered | | | |
## Other biologics

### Autoimmunity

<table>
<thead>
<tr>
<th>Trial phase</th>
<th>Compound</th>
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<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 (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: 3mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose  
• Arm 2: 10mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose  
• Arm 3: 3mg MEDI4920 (n = 3) or placebo (n = 2) as a single IV dose  
• Arm 4: 100mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose  
• Arm 5: 300mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose  
• Arm 6: 1000mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose  
• Arm 7: 2000mg 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 |
| Phase I    | Anti-ILT7 (MEDI7734) | Patients with Type I Interferon-Mediated Autoimmune Diseases: Dermatomyositis, Polymyositis, Sjogren’s Syndrome, Systemic Lupus Erythematosus, Systemic Sclerosis | N = 36 | • Arm 1: 1mg MEDI7734 (n = 3) or placebo (n = 1) as a single SC dose  
• Arm 2: 5mg MEDI7734 (n = 6) or placebo (n = 2) as a single SC dose  
• Arm 3: 15mg MEDI7734 (n = 6) or placebo (n = 2) as a single SC dose  
• Arm 4: 50mg MEDI7734 (n = 6) or placebo (n = 2) as a single SC dose  
• Arm 5: 150mg MEDI7734 (n = 6) or placebo (n = 2) as a single SC dose | • Safety, tolerability  
• Pharmacokinetics and pharmacodynamics | • FPD H2 2016  
• LPCD: H2 2017  
• Estimated top-line results: 2017 |
### 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>
</table>
| Phase IIA   | rhLCAT   | Adults with stable coronary artery disease (CAD) and low High-density lipoprotein (HDL) | N = 56 | • SAD in stable CAD patients | • Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, immunogenicity and physical examination  
• Changes in baseline adjusted post dose HDL-C | • FPD: Q4 2015  
• LPCD: Q2 2016  
• Top-line results: H2 2016 |
| Phase I     | rhLCAT   | Adults with stable coronary artery disease and low HDL | N = 16 | • SAD IV | • Safety  
• Changes in total HDL  
• Change in Cholesteryl Ester | • Completed by Alphacore |
| Phase I     | GLP-1-Glu | Healthy male subjects | N = 64 | • SAD SC administration  
• Germany | • Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination | • FPD: Q1 2015  
• LPCD: Q4 2015  
• Top-line results: Q4 2015  
• Complete |
| Phase I     | GLP-1-Glu | Healthy male subjects | N = 64 | • SAD SC administration  
• Germany | • Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination | • FPD: Q1 2015  
• LPCD: Q4 2015  
• Top-line results: Q4 2015  
• Complete |
| Phase I     | GLP-1-Glu | Male Adults with type-2 diabetes | N = 75 | • MAD SC administration  
• Germany | • Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination  
• Efficacy: MMT glucose AUC, HbA1c, fructosamine and body weight loss | • FPD: Q1 2016  
• LPCD: H2 2016  
• Top-line results: 2017 |
| Phase IIa   | MEDI4166  | Adults with type-2 diabetes | N = 124 | • SAD/MAD SC administration Part A (Ph1)  
• Safety/tolerability following SC dosing of 4166  
Part B (Ph2a)  
• Characterise the effect of multiple-ascending SC doses on glucose metabolism following an MMTT as measured by glucose AUC  
• Characterise the effect of multiple-ascending SC doses on LDL-c level | • FPD: Q4 2015  
• LPCD: H2 2016  
• Estimated top-line results: H2 2016 |
## 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>
</table>
| Phase III | PD-L1 (durvalumab) | Solid tumours | N = 1,014 | • Dose Escalation: 5 cohorts at Q2W and 1 cohort at Q3W  
• Dose Expansion: 16 tumour type cohorts at the Q2W MTD defined during dose escalation; one cohort at 20mg Q4W  
Global trial – eight countries | • Safety  
• Optimal biologic dose  
• Secondary endpoints include PK, immunogenicity and antitumour activity | • FPD: Q3 2012  
• LPCD: Q4 2015  
• Estimated top-line results: 2017 |
| Phase I | PD-L1, azacitidine (durvalumab, Vidaza) | Myelodysplastic syndrome | N = 41 | Dose-escalation and dose-expansion trial  
• Arm 1: durvalumab  
Global trial – four countries | • Safety and tolerability of monotherapy and combination  
• Secondary endpoints include duration of response, PFS and OS | • FPD: Q2 2014  
• LPCD: Q2 2015  
• Estimated top-line results: 2017 |
## Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)
### Solid and hematologic 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 = 236 | • 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 = 144 | • 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 = 446 | • Dose Escalation: minimum 5 cohorts exploring various treme  
Q4W and durvalumab 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 = 380 | • Dose Exploration: 2 cohorts exploring various Q4W treme and durvalumab dose combinations and 2 cohorts exploring various Q2W treme and durvalumab 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 anti-tumour 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-naive, PD-L1+, combo  
• Arm B: treatment-naive, PD-L1+, combo  
• Arm C: PD-1/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: Q1 2016  
• Estimated top-line results: 2017 |
| Phase Ib | Diffuse Large B-cell Lymphoma | N = 186 | • Arm A: durvalumab  
• Arm B: durvalumab + tremelimumab  
• Arm C: tremelimumab + AZD9150 US and European trial centres | • Safety & tolerability  
• Secondary endpoints include OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers | FPD: Q3 2016  
• LPCD: H2 2018  
• Estimated top-line results: 2021 |
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) + durvalumab IV  
Expansion phase  
• *Iressa* (QD) + durvalumab 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: 2019 |

*Notes:*
- FPD: First Public Disclosure
- LPCD: Late Public Disclosure
## Melanoma

### Durvalumab (MEDI4736; PD-L1 mAb) + Tafinlar (dabrafenib)/ Mekinist (trametinib)

<table>
<thead>
<tr>
<th>Trial phase</th>
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<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Phase I/II** | Metastatic or unresectable melanoma | N = 69 | Dose Escalation:  
  - Cohort A: dabrafenib 150mg BID/ trametinib 2mg QD/ durvalumab IV  
  - Cohort B: trametinib 2mg QD/ durvalumab IV  
  - Cohort C: trametinib 2mg QD/ durvalumab IV  
  Dose Expansion:  
  - Each cohort will be expanded at the MTD to enroll a total of 20 subjects per cohort  
  Global trial – two countries | • 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 | **FPD: Q1 2014**  
**LPCD: Q2 2015**  
**Estimated top-line results: 2017** |

**NCT02027961**
# 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 (escalation phase) | N = 150 | Dose-escalation phase  
• Durvalumab IV + MEDI0680 IV  
Dose-expansion phase at selected dose from dose-escalation phase  
• Durvalumab 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 | RCC (expansion phase) | | | | |

## Patient population and design

- **Number of patients**: N = 150
- **Design**:
  - **Dose-escalation phase**:
    - Durvalumab IV + MEDI0680 IV
  - **Dose-expansion phase at selected dose from dose-escalation phase**:
    - Durvalumab IV + MEDI0680 IV recommended dose

## Endpoints

- Safety
- Determination of MTD
- Secondary endpoints include tumour response such as objective response rate, disease control rate, progression-free survival, duration of response, OS, immunogenicity, pharmacokinetics, pharmacodynamics

## Status

- **FPD**: Q2 2014
- **LPCD**: Q3 2015
- **Estimated top-line results**: 2018
MEDI0562 (OX40 mAb)
MEDI0562 (OX40 mAb) + durvalumab (MEDI4736; PD-L1)
or tremelimumab (CTLA-4 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 malignancies</td>
<td>N = 196</td>
<td>Dose-escalation phase</td>
<td>• Safety</td>
<td>FPD: Q1 2015</td>
</tr>
<tr>
<td>NCT02318394</td>
<td></td>
<td></td>
<td>• MEDI0562 IV</td>
<td>• Determination of MTD</td>
<td>LPCD: 2017</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dose-expansion phase</td>
<td>• Secondary endpoints include preliminary anti-tumour activity, pharmacokinetics, biomarker activity, and immunogenicity</td>
<td>Estimated top-line results: 2017</td>
</tr>
<tr>
<td>Phase I</td>
<td>Advanced malignancies</td>
<td>N = 364</td>
<td>• ARM A: MEDI0562 IV + durvalumab IV</td>
<td>• Safety</td>
<td>FPD: Q2 2016</td>
</tr>
<tr>
<td>NCT02705482</td>
<td></td>
<td></td>
<td>• ARM B: MEDI0562 IV + tremelimumab IV</td>
<td>• Secondary endpoints include preliminary anti-tumour activity, pharmacokinetics, and immunogenicity</td>
<td>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>
<tbody>
<tr>
<td>NCT02221960</td>
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<td>• MEDI6383 IV</td>
<td>Determination of MTD</td>
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<td></td>
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<td></td>
<td>• MEDI6383 IV + durvalumab IV</td>
<td>Secondary endpoints include anti-tumour activity,</td>
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<td></td>
<td>Dose-expansion phase</td>
<td>pharmacokinetics, Biomarker activity, and</td>
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<td></td>
<td>• MEDI6383 IV recommended dose</td>
<td>immunogenicity</td>
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<td></td>
<td></td>
<td></td>
<td>• MEDI6383 IV + durvalumab IV recommended dose</td>
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<td></td>
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<td>US-only trial</td>
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</tbody>
</table>
## 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>
<tbody>
<tr>
<td><strong>Phase II</strong>&lt;br&gt;NCT01453205</td>
<td>Adults with relapsed or refractory B-cell diffuse large B-cell lymphoma</td>
<td>N = 170</td>
<td>• Arm 1: MEDI-551 dose level 1 and ICE/DHAP&lt;br&gt;• Arm 2: MEDI-551 dose level 2 and ICE/DHAP&lt;br&gt;• Arm 2: Rituxan + ICE/DHAP Open-label trial</td>
<td>• ORR, including Complete Response (CR) or Partial Response (PR)</td>
<td>• FPD: Q1 2012&lt;br&gt;• LPCD: Q2 2016&lt;br&gt;• Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td><strong>Phase I</strong>&lt;br&gt;NCT01957579</td>
<td>Adults with relapsed or refractory B-cell malignancies</td>
<td>N = 18</td>
<td>• Dose-escalation trial IV&lt;br&gt;Conducted in Japan</td>
<td>• MTD and efficacy</td>
<td>• FPD: Q2 2011&lt;br&gt;• LPCD: Q3 2015&lt;br&gt;• Top-line results: Q3 2015&lt;br&gt;• completed</td>
</tr>
</tbody>
</table>
## 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</td>
<td>• Safety</td>
<td>• FPD: Q4 2015</td>
</tr>
<tr>
<td>NCT02583165</td>
<td></td>
<td></td>
<td>• MEDI1873 IV</td>
<td>• Determination of MTD</td>
<td>• LPCD: H2 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>US trial centres</td>
<td>• Secondary endpoints include preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity</td>
<td>• 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>
</table>
| Phase I     | Advanced HER2+ metastatic breast and gastric cancer | Dose escalation N = 21-36
Dose expansion N = 80 | • First-time-in-human Phase 1, multi-centre, open-label, single-arm, dose-escalation, and dose-expansion trial for adult subjects | • Primary: safety
• Secondary endpoints include anti-tumour activity, overall response, disease control, PFS, OS and change from baseline tumour size | • FPD: Q4 2015
• LPCD: 2017
• Estimated top-line results: 2019 |
| NCT02576548 |                    |                    |        |           |        |

103
# 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>
<tbody>
<tr>
<td>Phase I</td>
<td>Advanced solid tumour malignancies readily accessible for injection</td>
<td>N = 43</td>
<td>Dose-escalation phase • MEDI9197 IT US trial centres- Ex US under evaluation</td>
<td>• Safety • Determination of MTD • Secondary endpoints include: – Objective response, disease control and duration of response. – Intra-tumoural and systemic PK and PD profiles/relationships</td>
<td>• FPD: Q4 2015 • LPCD: 2017 • Estimated top-line results: 2018</td>
</tr>
</tbody>
</table>

**Note:**
- **Lifecycle management**
- **Late-stage development**
- **Early development - IMED**
- **Early development - MedImmune**
## 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>
<tbody>
<tr>
<td>Phase I</td>
<td>Advanced malignancies</td>
<td>N = 188</td>
<td>Dose-escalation phase</td>
<td>• Safety</td>
<td>• FPD: Q3 2015</td>
</tr>
<tr>
<td>NCT02503774</td>
<td></td>
<td></td>
<td>• MEDI9447 IV</td>
<td>• Determination of MTD</td>
<td>• LPCD: 2018</td>
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<tr>
<td></td>
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<td></td>
<td>• MEDI9447 IV + durvalumab IV</td>
<td>• Secondary endpoints include preliminary anti-tumour activity, pharmacokinetics, pharmacodynamics, and immunogenicity</td>
<td>• Estimated top-line results: 2019</td>
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<td>Dose—expansion phase</td>
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<td>• MEDI9447 IV recommended dose</td>
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<td></td>
<td>• MEDI9447 IV recommended dose + Durvalumab IV</td>
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<td>US and Australian trial centres</td>
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</table>

**US and Australian trial centres**
## Other biologics

### 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 III  | 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 | • PFS | • FPD: Q2 2012  
• LPCD: Q2 2013  
• Estimated top-line results: 2017 |
| NCT01446159 | | | | • Arm 2: Aromatase Inhibitor alone Open label trial | • Retrospective evaluation of predictive biomarker +ve subgroups | |
| 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) |
| NCT01248949 | | 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 | | | |
# Other biologics

## 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>
<tbody>
<tr>
<td>Phase I NCT01284231 Partnered</td>
<td>Anti-CEA BiTE mAb (MEDI-565)</td>
<td>Adults with gastrointestinal (GI) adenocarcinoma with no available standard or curative treatments. Refractory pancreatic, colorectal and gastro-esophageal cancers</td>
<td>N = 51 max N = 60 max, 20 in each cohort</td>
<td>• Dose-escalation (3+3), IV • Dose expansion trial, IV</td>
<td>• MTD and safety profile</td>
<td>• FPD: Q1 11 • LPCD Q3 2014 • Top-line results: Q1 2015 • Completed</td>
</tr>
<tr>
<td>Phase I NCT01577745</td>
<td>Anti-DLL4 mAb (MEDI0639)</td>
<td>Adults with advanced solid tumours including SCLC</td>
<td>N = up to 28</td>
<td>• Dose-escalation trial (3+3); IV</td>
<td>• MTD and safety profile</td>
<td>• FPD: Q2 2012 • LPCD: Q2 2015 • Estimated top-line results: Q4 2015 • Completed</td>
</tr>
</tbody>
</table>
# 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>
</table>
| Phase I     | Alzheimer’s disease & healthy elderly | N = 121            | • SAD & MAD  
• Up to 10 iv cohorts are planned vs. placebo  
• 2 SC cohorts are planned vs. placebo  
US only | • Safety, tolerability | • FPD: Q2 2014  
• LPCD: Q2 2016  
• Estimated top-line results: H2 2016 |
MEDI7352 (NGF TNF Bispecific)
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>Painful osteoarthritis of the knee</td>
<td>N = 160</td>
<td>• SAD &amp; MAD</td>
<td>Safety, tolerability, PK, PD</td>
<td>• FPD: Q1 2016</td>
</tr>
<tr>
<td>NCT02508155</td>
<td></td>
<td></td>
<td>• Up to 10 iv cohorts are planned vs. placebo</td>
<td></td>
<td>• LPCD: H1 2017</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 2017</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Europe only</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# 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 | Healthy Japanese 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 Quadrivalent | | | | |
| Phase III   | MEDI3250 | Healthy Japanese 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; LPCD: 2017; Estimated top-line results: 2017</td>
</tr>
<tr>
<td>Phase II</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; LPCD: Q2 2016; Estimated top-line results: H2 2016</td>
</tr>
<tr>
<td>Phase III</td>
<td>Phase IIA</td>
<td>NCT0114268</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>
</tr>
<tr>
<td>Phase IIB/IIIA</td>
<td>NCT02930340</td>
<td>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>FPD: Q2 2014; LPCD: Q2 2014; Top-line results: Q2 2015 (completed)</td>
</tr>
<tr>
<td>Phase I</td>
<td>NCT02350751</td>
<td>Healthy adults</td>
<td>N = 40</td>
<td>Double-blind, Single-dose, Placebo-controlled, Dose-escalation trial</td>
<td>Evaluate the safety and pharmacokinetics</td>
<td>FPD: Q1 2015; LPCD: Q1 2015; Top-line results: Q2 2015 (completed)</td>
</tr>
<tr>
<td>Phase IIB/IIIA</td>
<td>NCT02255760</td>
<td>Healthy adults</td>
<td>N = 56</td>
<td>Randomised, Double-blind, Placebo-Controlled, Dose-Escalation trial</td>
<td>Evaluate the safety, tolerability, and pharmacokinetics</td>
<td>FPD: Q3 2014; LPCD: Q1 2015; Top-line results: Q2 2015 (completed)</td>
</tr>
<tr>
<td>Phase II</td>
<td>NCT02696902</td>
<td>Intubated ICU</td>
<td>N = 429</td>
<td>Placebo-controlled, single-dose, dose-ranging</td>
<td>Efficacy and safety</td>
<td>FPD: H1 2016; LPCD: 2016; Estimated top-line results: 2018</td>
</tr>
</tbody>
</table>
Clinical trials appendix
Q2 2016 update