AstraZeneca

LCM development programmes

Q1 2014
# BRILINTA/BRILIQUE (ADP receptor antagonist)

## PARTHENON development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Patients with prior MI | Phase III PEGASUS NCT01225562 | N = 21000 | • ARM 1: Ticagrelor 90 mg BD  
• ARM 2: Ticagrelor 60 mg BD  
• ARM 3: Placebo on a background of ASA | • Composite of CV death, non-fatal NI, or non-fatal stroke. | • FSI Q4 10  
• LSI Q2 13  
• Est. completion date Q4 14  
• Est. external presentation Q3 2015 (ESC) |
| Patients with PAD | Phase III EUCLID NCT01732822 | N = 13500 | • ARM 1: Ticagrelor 90 mg BD  
• ARM 2: Clopidogrel 75 mg QD monotherapy trial | • Composite of CV death, MI and ischemic stroke | • FSI Q4 12  
• LSI Q1 14  
• Est. completion date Q1 16 |
| Patients with Stroke or TIA | Phase III SOCRATES NCT01994720 | N = 9600 | • ARM 1: Ticagrelor 90 mg BD  
• ARM 2: ASA 100mg day monotherapy trial | • Composite of stroke, MI or death | • FSI Q1 14  
• Est. completion date Q4 15 |
| Patients with Type 2 Diabetes and Coronary Artery Disease without a previous history of MI or Stroke | Phase III THEMIS NCT01991795 | N = 17000 | • ARM 1: Ticagrelor 90 mg BD  
• ARM 2: Placebo on a background of ASA if not contra indicated or not tolerated | • Composite of CV death, MI or stroke | • FSI planned to Q1 14  
• Est. completion date Q1 17 |
## Forxiga/Farxiga (SGLT-2 inhibitor)

### Type 2 Diabetes development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typ 2 diabetes mellitus with high risk for CV event</td>
<td>Phase III/IV DECLARE NCT01730534</td>
<td>N = 17150</td>
<td><strong>ARM 1</strong>: Dapagliflozin 10 mg QD + standard of care therapy&lt;br&gt;<strong>ARM 2</strong>: Placebo + standard of care therapy for Type 2 Diabetes&lt;br&gt;Global study – 32 countries</td>
<td><strong>Time to first event included in the composite endpoint of CV death, MI or ischemic stroke</strong></td>
<td>• FSI Q2 13&lt;br&gt;• LSI Q2 16&lt;br&gt;• LSLV Q2 19&lt;br&gt;• Est. completion date Q3 19&lt;br&gt;• Est. external presentation 2020</td>
</tr>
</tbody>
</table>
Saxagliptin/Dapagliflozin (DPP-4/SGLT-2 inhibitors)

FDC Type 2 Diabetes development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status*</th>
</tr>
</thead>
</table>
| Type 2 Diabetes Mellitus | Phase III NCT01606007 | N = 516 | • ARM 1: Saxa 5 mg + Met XR  
• ARM 2: Dapa 10 mg + Met XR  
• ARM 3: Saxa 5 mg + Dapa 10 mg + Met XR  
Global study – 8 countries | • HbA1C reduction at 24 week | • FSI Q3 12  
• LSI Q2 13  
• Est. completion date Q1 14  
• Targeted as Late Breaking abstract ADA June 2014 |
| Type 2 Diabetes Mellitus | Phase III NCT01619059 | N = 280 | • ARM 1: Saxa 5 mg + Dapa 10 mg + Met IR  
• ARM 2: Placebo + Dapa 10 mg + Met IR  
Global study – 8 countries | • HbA1C reduction at 24 week | • FSI Q2 12  
• Est. Primary completion date Q2 14  
• Est. Study completion date Q1 15  
• Est. external presentation Q2 15 |
| Type 2 Diabetes Mellitus | Phase III NCT01646320 | N = 280 | • ARM 1: Dapa 10 mg + Saxa 5 mg + Met IR  
• ARM 2: Placebo + Saxa 5 mg + Met IR  
Global study – 7 countries | • HbA1C reduction at 24 week | • FSI Sep 2012  
• Est. Primary completion date Q4 14  
• Est. Study completion date Q4 15 |

*studies performed by BMS
<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Type 2 Diabetes** | **Phase III DURATION-NEO 1** | N = 375 | • ARM 1: Byetta  
• ARM 2: Exenatide weekly suspension  
On a background of diet & exercise alone or with stable regimen of oral antidiabetes  
US only | • Change in HbA1c from baseline at 28 weeks (52 week OLE) | • FSI Q1 13  
• LSI Q2 13  
• Est. completion date Q2 14  
• Est. external presentation 2014 (EASD) or 2015 (ADA)  
• Est. filing 2015 |
| **Type 2 Diabetes** | **Phase III DURATION-NEO 2** | N = 360 | • ARM 1: Sitagliptin  
• ARM 2: Exenatide weekly suspension  
• ARM 3: Placebo  
On a background of diet & exercise alone or with stable regimen of oral antidiabetes  
US only | • Change in HbA1c from baseline at 28 weeks | • FSI Q1 13  
• LSI Q3 13  
• Est. completion date Q3 14  
• Est. external presentation 2014 (EASD) or 2015 (ADA) |
| **Type 2 Diabetes** | **Phase IV EXSCEL** | N = 14000 | • ARM 1: Bydureon once weekly 2mg  
• ARM 2: Placebo  
On a background of standard of care medication, different degree of CV risk  
Global study | • Time to first confirmed CV event in the primary composite CV endpoint (CV death, non-fatal MI, non-fatal stroke) | • FSI Q2 10  
• Est completion date 2018 |
# IRESSA (EGFR TKI)

## EGFR M+ NSCLC development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
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</tr>
</thead>
</table>
| EGFR M+ NSCLC who have progressed on 1st line IRESSA | Phase III IMPRESS (NCT01544179) | N = 289 | **ARM 1**: Gefitinib 250 mg QD + max 6 cycles of cisplatin and pemetrexed  
**ARM 2**: Placebo + max 6 cycles of cisplatin and pemetrexed  
Global study – 11 countries | Progression Free Survival  
Overall Survival is a secondary endpoint. | FSI Q1 12  
LSI Q4 13  
Est completion date Q1 15 |
| EGFR M+ NSCLC who failed 1st line EGFR TKI and Chemo OR not suitable for chemo | Phase I (NCT02040064) | N = 18-24 | **Cohort 1**: Gefitinib 250mg + Treme 3 mg/kg*  
**Cohort 2**: Gefitinib 250mg + Treme 6 mg/kg*  
**Cohort 3**: Gefitinib 250mg + Treme 10 mg/kg*  
*Tremelimumab is given QM for first 6 months thereafter Q3M  
3 Sites: IGR (Paris), Marseille, Toulouse | Determine the RP2D for Tremelimumab and associated DLTs of the combination | FSI Q1 14  
Interim report June 2015  
LSI Q4 15  
Est completion date 2018 |
# Faslodex (oestrogen receptor antagonist) Breast cancer development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| 1st line postmenopausal HR+ locally advanced or metastatic breast cancer, with no prior hormonal therapy | Phase III FALCON NCT01602380 | N = 605 | ARM 1: Faslodex 500 mg (+ oral placebo)  
ARM 2: Arimidex 1 mg (+ placebo injection)  
Global study – 21 countries | Progression Free Survival  
Overall Survival is a secondary endpoint | FSI Oct 2012  
LSI Oct 2014  
Est. completion date Q2 16  
Est. external presentation H2 16 |
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Late stage development programmes

Q1 2014
**Epanova (prescription grade Omega-3 free fatty acid EPA+DHA)**

**Hypertriglyceridemia development programme**

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe hypertriglyceridemia</td>
<td>Phase III EVOLVE II NCT02009865</td>
<td>N = 104</td>
<td>ARM 1: Epanova 2g QD</td>
<td>Change in serum triglycerides over 12 weeks</td>
<td>• FSI Q4 13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 2: Placebo (olive oil)</td>
<td></td>
<td>• LSI Q4 14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Global study – 7 countries</td>
<td></td>
<td>• Est primary completion Q4 14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Est completion date Q4 15</td>
</tr>
</tbody>
</table>
Metreleptin (recombinant leptin analogue)

Lipidystrophy development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoints</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipodystrophy</td>
<td>Phase III NIH / NIDDK</td>
<td>N = 72*</td>
<td>• ARM 1: Metreleptin</td>
<td>• Glycaemic control</td>
<td>• Ongoing</td>
</tr>
<tr>
<td></td>
<td>ISS</td>
<td></td>
<td>Open label treatment protocol</td>
<td>• Triglycerides</td>
<td>• Est. Completion date Q4 15</td>
</tr>
<tr>
<td></td>
<td>NCT01778556</td>
<td></td>
<td>NIH sponsored</td>
<td>• Various sub-protocols</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patients from multiple countries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipodystrophy with associated diabetes</td>
<td>Phase III FHA101</td>
<td>N = 28*</td>
<td>• ARM 1: Metreleptin</td>
<td>• Glycaemic control</td>
<td>• Ongoing</td>
</tr>
<tr>
<td>and/or hyper-triglyceridaemia</td>
<td>NCT00677313</td>
<td></td>
<td>Open label treatment protocol</td>
<td>• Triglycerides</td>
<td>• Est. Completion date Q2 14</td>
</tr>
</tbody>
</table>

* Relates to data-cut for BLA submission: studies are ongoing
## Benralizumab (anti-IL5Rα)

### Asthma development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA ± chronic OCS | Phase III CALIMA NCT01914757 | N = 1026       | • ARM 1: 30 mg Q8wk  
• ARM 2: 30 mg Q4wk  
• ARM 3: Placebo  
56-week study  
Global study – 9 countries | • Rate of Asthma Exacerbations  
• Est completion date Q1 16 |                                                            |
| Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA ± chronic OCS | Phase III SIROCCO NCT01928771 | N = 1134       | • ARM 1: 30 mg Q8wk  
• ARM 2: 30 mg Q4wk  
• ARM 3: Placebo  
48-week study  
Global study – 14 countries | • Rate of Asthma Exacerbations  
• Est completion date Q1 16 |                                                            |
| Severe asthma, inadequately controlled despite background controller medication MD ICS + LABA ± chronic OCS | Phase III PAMPERO NCT01947946 | N = 1410       | • ARM 1: 30 mg Q8wk  
• ARM 2: 30 mg Q4wk  
• ARM 3: Placebo  
48-week study  
Global study – 12 countries | • Rate of Asthma Exacerbations  
• Est completion date Q1 16 |                                                            |
## PT003 (LABA/LAMA) & PT001 (LAMA) COPD COPD development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Moderate to Very Severe COPD** | Phase III PINNACLE 1 NCT01854645 | N = 1751 | ARM 1: GF MDI (PT003) 14.4/9.6 μg  
ARM 2: G MDI (PT001) 14.4 μg  
ARM 3: F MDI (PT005) 9.6 μg  
ARM 4: Open-label tiotropium bromide inhalation powder  
ARM 5: Placebo MDI | • Change from baseline in morning pre-dose trough FEV₁ | 24 week study  
• FSI Q2 13  
• LSI Q1 14  
• Est completion date Q4 14 |
| **Moderate to Very Severe COPD** | Phase III PINNACLE 2 NCT01854658 | N = 1376 | ARM 1: GF MDI (PT003) 14.4/9.6 μg  
ARM 2: G MDI (PT001) 14.4 μg  
ARM 3: F MDI (PT005) 9.6 μg  
ARM 4: Placebo MDI | • Change from baseline in morning pre-dose trough FEV₁ | 24 week study  
• FSI Q3 13  
• LSI Q2 14  
• Est completion date Q1 15 |
| **Moderate to Very Severe COPD** | Phase III PINNACLE 3 NCT01970878 | N = 850 | ARM 1: GF MDI (PT003) 14.4/9.6 μg  
ARM 2: G MDI (PT001) 14.4 μg  
ARM 3: F MDI (PT005) 9.6 μg  
ARM 4: Open-label tiotropium bromide inhalation powder | • Overall safety, tolerability and efficacy | 28 week extension  
• FSI Q4 13  
• LSI Q2 14  
• Est completion date Q1 15 |
Brodalumab (anti-IL-17RA)

Inflammatory diseases development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate to severe plaque psoriasis</td>
<td>Phase III AMAGINE-1</td>
<td>N = 661</td>
<td>ARM 1: 210 mg brodalumab</td>
<td>PASI at wk 12</td>
<td>FSI Q3 12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 2: 140 mg brodalumab</td>
<td>Static physician’s global assessment (sPGA) at wk 12</td>
<td>Est completion date Q2 14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 3: placebo</td>
<td></td>
<td>Est external presentation Q4 14 (EADV)</td>
</tr>
<tr>
<td></td>
<td>NCT01708590</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate to severe plaque psoriasis</td>
<td>Phase III AMAGINE-2</td>
<td>N = 1800</td>
<td>ARM 1: 210 mg brodalumab</td>
<td>PASI at wk 12</td>
<td>FSI Q3 12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 2: 140 mg brodalumab</td>
<td>Static physician’s global assessment (sPGA) at wk 12</td>
<td>Est completion date Q4 14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 3: ustekinumab</td>
<td></td>
<td>Est external presentation Q1 15 (AAD)</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>ARM 4: placebo</td>
<td></td>
<td></td>
</tr>
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<td></td>
<td>NCT01708603</td>
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</tr>
<tr>
<td>Moderate to severe plaque psoriasis</td>
<td>Phase III AMAGINE-3</td>
<td>N = 1881</td>
<td>ARM 1: 210 mg brodalumab</td>
<td>PASI at wk 12</td>
<td>FSI Q3 12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 2: 140 mg brodalumab</td>
<td>Static physician’s global assessment (sPGA) at wk 12</td>
<td>Est completion date Q4 14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 3: ustekinumab</td>
<td></td>
<td>Est external presentation Q1 15 (AAD)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 4: placebo</td>
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</tr>
<tr>
<td></td>
<td>NCT01708629</td>
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<tr>
<td>Moderate to severe PsA</td>
<td>Phase II</td>
<td>N = 156</td>
<td>ARM 1: 280 mg brodalumab</td>
<td>ACR20 response at wk 12</td>
<td>Primary data Q4 12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 2: 140 mg brodalumab</td>
<td></td>
<td>OLE ongoing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 3: placebo</td>
<td></td>
<td>FSI Q1 14</td>
</tr>
<tr>
<td>Moderate to severe inadequately controlled high reversibility asthma</td>
<td>Phase II</td>
<td>N = 566</td>
<td>ARM 1: 210 mg brodalumab</td>
<td>Change in ACQ at wk 24</td>
<td>FSI Q2 13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ARM 2: placebo</td>
<td></td>
<td>Est completion date Q2 15</td>
</tr>
</tbody>
</table>
Lesinurad (URAT1 inhibitor)
Gout development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary endpoint</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gout with Inadequate Hypouricemic Response to Allopurinol</td>
<td>Phase III CLEAR 1</td>
<td>N = 600</td>
<td>Arm 1: Placebo • Arm 2: lesinurad 200 mg QD • Arm 3: lesinurad 400 mg QD All arms: SOC allopurinol QD</td>
<td>Proportion of subjects with an sUA level that is &lt; 6.0 mg/dL by Month 6</td>
<td>FSI Q1 12 • LSI Q3 13 • Est completion date Q2 14 • Est external presentation Q4 14 (ACR)</td>
</tr>
<tr>
<td>Gout with Inadequate Hypouricemic Response to Allopurinol</td>
<td>Phase III CLEAR 2</td>
<td>N = 600</td>
<td>Arm 1: Placebo • Arm 2: lesinurad 200 mg QD • Arm 3: lesinurad 400 mg QD All arms: SOC allopurinol QD</td>
<td>Proportion of subjects with an sUA level that is &lt; 6.0 mg/dL by Month 6</td>
<td>FSI Q4 11 • LSI Q2 13 • Est completion date Q2 14 • Est external presentation Q4 14 (ACR)</td>
</tr>
<tr>
<td>Tophaceous Gout</td>
<td>Phase III CRYSTAL</td>
<td>N = 315</td>
<td>Arm 1: Placebo • Arm 2: lesinurad 200 mg QD • Arm 3: lesinurad 400 mg QD All arms: febuxostat 80 mg QD</td>
<td>Proportion of subjects with an sUA level that is &lt; 5.0 mg/dL by Month 6</td>
<td>FSI Q1 12 • LSI Q2 13 • Est completion date Q2 14 • Est external presentation Q4 14 (ACR)</td>
</tr>
<tr>
<td>Gout with Intolerance or Contraindication to a Xanthine Oxidase Inhibitor</td>
<td>Phase III LIGHT</td>
<td>N = 200</td>
<td>Arm 1: Placebo • Arm 2: lesinurad 400 mg QD</td>
<td>Proportion of subjects with an sUA level that is &lt; 6.0 mg/dL by Month 6</td>
<td>FSI Q1 12 • LSI Q2 13 • Est completion date Q4 13 • Est external presentation Q4 14 (ACR)</td>
</tr>
<tr>
<td>Gout previously enrolled LIGHT study</td>
<td>Phase III LIGHT OLE</td>
<td>N ≤ 200</td>
<td>All arms: open-label lesinurad 400 mg QD</td>
<td>Assess the long-term efficacy and safety of lesinurad monotherapy.</td>
<td>FSI Q4 12 • Recruitment ongoing</td>
</tr>
<tr>
<td>Gout previously enrolled in studies CLEAR 1 &amp; 2</td>
<td>Phase III CLEAR OLE</td>
<td>N ≤ 200</td>
<td>Arm 1: lesinurad 200 mg QD • Arm 2: lesinurad 400 mg QD All arms: SOC allopurinol QD</td>
<td>Assess the long-term efficacy and safety of lesinurad in combination with allopurinol.</td>
<td>FSI Q1 13 • Recruitment ongoing</td>
</tr>
<tr>
<td>Gout previously enrolled in CRYSTAL study</td>
<td>Phase III CRYSTAL</td>
<td>N ≤ 315</td>
<td>Arm 1: lesinurad 200 mg QD • Arm 2: lesinurad 400 mg QD All arms: febuxostat 80 mg QD</td>
<td>Assess the long-term efficacy and safety of lesinurad in combination with febuxostat.</td>
<td>FSI Q1 13 • Recruitment ongoing</td>
</tr>
</tbody>
</table>
# Olaparib (PARP inhibitor)

## Ovarian and gastric cancer development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| PSR gBRCAm ovarian cancer | Phase III SOLO-2\[NCT01874353\] | N = 264 | • ARM 1: olaparib tablet 300 mg BD maintenance therapy until progression  
• ARM 2: placebo  
Global study – 13 countries | • Progression Free Survival  
• Overall Survival is a secondary endpoint. | • FSI Q3 13  
• LSI Q1 15  
• Est completion date Q3 15  
• Est external presentation Q2 16 (ASCO) |
| 1<sup>st</sup> line gBRCAm ovarian cancer | Phase III SOLO-1\[NCT01844986\] | N = 344 | • ARM 1: olaparib tablet 300 mg BD maintenance therapy for 2 years or until disease progression  
• ARM 2: placebo  
Global study – 14 countries | • Progression Free Survival  
• Overall Survival is a secondary endpoint. | • FSI Q3 13  
• LSI Q1 15  
• Est completion date Q3 16  
• Est external presentation Q2 17 |
| 2<sup>nd</sup> line gastric cancer (all comers with a co-primary sub population) | Phase III GOLD\[NCT01924533\] | N = 500 | • ARM 1: paclitaxel + olaparib until progression  
• ARM 2: paclitaxel + placebo  
olaparib dose 100mg BD throughout paclitaxel dose cycle & 300 mg BD post cycle  
The study will be conducted in Korea, China and Japan | • Overall Survival | • FSI Q3 13  
• LSI Q3 15  
• Est completion date Q4 16  
• Est external presentation Q3 17 |
# Selumetinib (AZD6244, ARRY142886) (MEK-inhibitor)

## Solid tumours development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| 2nd Line KRASm NSCLC | Phase III SELECT-1 | N = 634 | - **ARM 1**: Selumetinib 75mg BD + docetaxel 75 mg/m^2 intravenously administered on day 1 of each 21 day cycle  
- **ARM 2**: Placebo BD + docetaxel 75 mg/m^2 intravenously administered on day 1 of each 21 day cycle  
Global study – 26 countries | - Progression Free Survival  
- Overall Survival is a secondary endpoint. | • FSI Q4 13  
• LSI Q1 16  
• Est completion date Q3 16  
• Est external presentation Q2 17 |
| Metastatic Uveal Melanoma | Phase II SUMIT | N = 128 | - **ARM 1**: Selumetinib 75 mg BD + dacarbazine 1000 mg/m^2 day 1 of every 21 day cycle  
- **ARM 2**: Placebo BD + dacarbazine 1000 mg/m^2 day 1 of every 21 day cycle  
3:1 Randomisation  
Global study – 10 countries | - Progression Free Survival | • FSI Q1 14  
• LSI Q4 14  
• Est completion date Q2 15  
• Est external presentation Q4 15 |
| Differentiated Thyroid Cancer | Phase II ASTRA | N = 304 | - **ARM 1**: Selumetinib 75mg BD 5 weeks duration + RAI 100mCi  
- **ARM 2**: Placebo BD 5 weeks duration + RAI 100mCi  
Global study – 8 countries  
\(^3\) Single dose of 100mCi \(^{131}\)I administered following 4 weeks of selumetinib (or placebo). | - Complete remission (CR) rate at 18 months post-RAI  
- Clinical remission rate at 18 m post RAI (per SoC) | • FSI Q3 13  
• LSI Q3 14  
• Est completion date Q3 16  
• Est external presentation Q2 17 |
## CAZ-AVI (BLI/cephalosporin SBI)
### Serious infections development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Hospitalised patients with complicated intra-abdominal infections | Phase III RECLAIM-1 NCT01499290 | N = 523 | - **ARM 1**: CAZ-AVI (2000/500mg) plus Metronidazole  
- **ARM 2**: Meropenem | • Co primary of:  
(i) clinical response at TOC (MITT)  
(ii) clinical response at TOC (i.e. clinically evaluable) | • FSI Q1 12  
• LSI Q1 14  
• Est completion date Q2 14  
• Est external presentation Q2 15 (ECCMID) |
| Hospitalised patients with complicated intra-abdominal infections | Phase III RECLAIM-2 NCT01500239 | N = 582 | - **ARM 1**: CAZ-AVI (2000/500mg) plus Metronidazole  
- **ARM 2**: Meropenem | • Co primary of:  
(i) clinical response at TOC (MITT)  
(ii) clinical response at TOC (i.e. clinically evaluable) | • FSI Q2 12  
• LSI Q1 14  
• Est completion date Q2 14  
• Est external presentation Q2 15 (ECCMID) |
| Hospitalised Adults With complicated urinary tract Infections | Phase III RECAPTURE-1 NCT01595438 | N = 460 | - **ARM 1**: CAZ-AVI (2000/500mg) plus either 500 mg of Ciprofloxacin or 800 mg/160 mg of sulfamethoxazole/trimethoprim  
- **ARM 2**: Doripenem (500 mg) plus either 500 mg of Ciprofloxacin or 800 mg/160 mg of sulfamethoxazole/trimethoprim | • Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT) | • FSI Q4 12  
• LSI Q2 14  
• Est completion date Q4 14  
• Est external presentation Q3 15 (ICAAC) |
| Hospitalised patients with complicated urinary tract infections | Phase III RECAPTURE-2 NCT01599806 | N = 504 | - **ARM 1**: CAZ-AVI (2000/500mg) plus either 500 mg of Ciprofloxacin or 800 mg/160 mg of sulfamethoxazole/trimethoprim  
- **ARM 2**: Doripenem (500 mg) plus either 500 mg of Ciprofloxacin or 800 mg/160 mg of sulfamethoxazole/trimethoprim | • Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT) | • FSI Q4 12  
• LSI Q2 14  
• Est completion date Q4 14  
• Est external presentation Q3 15 (ICAAC) |
## CAZ-AVI (BLI/cephalosporin SBI)

### Serious infections development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Patients with complicated urinary tract infections and complicated intra-abdominal infections | Phase III REPRISE NCT01644643 | N = 400 | **ARM 1**: CAZ-AVI (2000/500mg) plus Metronidazole  
**ARM 2**: Best available therapy  
Global study – 31 countries | Patients with clinical cure at the Test of Cure visit in the microbiological intent to treat analysis set | FSI Q113  
LSI Q1 15  
Est completion date Q2 15  
Est external presentation Q1 16 |
| Hospitalised patients with complicated intra-abdominal infections | Phase III RECLAIM-3 NCT01726023 | N = 404 | **ARM 1**: CAZ-AVI (2000/500mg) plus Metronidazole  
**ARM 2**: Meropenem  
Asia-focused study – 3 countries (China, Vietnam & Korea) | Clinical Cure at the TOC visit in the Clinically Evaluable (CE) analysis set | FSI Q1 13  
LSI Q4 14  
Est completion date Q1 15  
Est external presentation Q4 15 |
| Hospitalised patients with nosocomial pneumonia infections, including hospital acquired pneumonia (HAP) and ventilator associated pneumonia (VAP) | Phase III REPROVE NCT01808092 | N = 1660 | **ARM 1**: CAZ-AVI (2000/500mg)  
**ARM 2**: Meropenem  
Global study – 24 countries | Proportion of patients with clinical cure at the TOC visit in the cMITT and CE analysis sets (co-primary analyses). | FSI Q2 13  
LSI Q2 16  
Est completion date Q3 16  
Est external presentation Q2 17 |
AstraZeneca
Early development programmes
Q1 2014
## AZD1722 (NHE3 inhibitor)

### ESRD & CKD development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| ESRD on hemodialysis | Phase IIa | N = 70 | **ARM 1:** AZD1722, starting dose 45 mg BD, down titration based on tolerability  
**ARM 2:** Placebo  
Conducted in the US | • Reduction in mean weekly interdialytic weight gain (IDWG) | • FSI Q1 13  
• LSI Q4 13  
• Est completion date Q1 14  
• Est external presentation Q4 14 |
| CKD with Type 2 Diabetes and Albuminuria | Phase IIa | N = 140 | **ARM 1:** AZD1722, starting dose 15 mg BD, dose escalation based on tolerability (max 60 mg BD)  
**ARM 2:** Placebo  
Conducted in the US, plans to expand into Germany | • Changes in Urine Albumin to Creatinine Ratio (UACR) | • FSI Q2 13  
• LSI Q3 14  
• Est completion date Q4 14  
• Est external presentation Q3 15 |
| Patients with constipation predominant Irritable Bowel Syndrome (IBS-C) | Phase IIb | N = 360 | **ARM 1:** AZD1722, 5 mg BD  
**ARM 2:** AZD1722, 20 mg BD  
**ARM 3:** AZD1722, 50 mg BD  
**ARM 4:** Placebo  
Conducted in the US | • Percent Complete Spontaneous Bowel Movement responders vs placebo | • FSI Q3 13  
• LSI Q2 14  
• Est completion date Q4 14  
• Est external presentation Q3 15 |
# AZD5069 (CXCR2)

## Asthma development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Adult patients with uncontrolled persistent asthma | Phase IIb NIMBUS  | N = 640       | • Arm 1: ICS/LABA + AZD5069 45mg  
• Arm 2: ICS/LABA + AZD5069 15mg  
• Arm 3: ICS/LABA + AZD5069 5mg  
• Arm 4: ICS/LABA + Placebo  
6 month treatment followed by an optional 6 month safety follow up | • Placebo adjusted effect of AZD5069 on rate of severe exacerbations  
• FSI Q4 12  
• Est completion Q2 14  
• Target late breaking abstract Q3 14 (ERS) |                                               |
| Adult patients with Bronchiectasis        | Phase IIa STRATUS | N = 52        | • Arm 1: AZD5069 80mg BD  
• Arm 2: Placebo  
28-Day Oral Administration, multiple centre | • Placebo adjusted effect of AZD5069 on reduction of sputum neutrophils  
• Study Completed  
• Estimated publication final data Q4 14 |                                               |
| Healthy Volunteers                        | Phase I NCT01480739 | N = 30        | • Arm 1: AZD5069 100 mg (50 mg x 2) BD for 7 days  
• Arm 2: Placebo 100 mg (50 mg x 2) BD for 7 days  
Two-way cross-over, single centre | • Effects on blood neutrophil numbers, function and recruitment after SC G-CSF injection and strenuous exercise  
• Study Completed  
• Est external presentation Q3 14 (ERS) |                                               |
| Healthy Volunteers                        | Phase I NCT01100047 | N = 69 + 33   | • Single ascending dose study  
• Eight different dose levels investigated  
• Multiple ascending dose study  
• Three different dose levels investigated | • Safety and tolerability  
• Study Completed  
• Estimated publication Q4 2014 |                                               |
| Healthy Volunteers Adult Japanese males   | Phase I NCT01100047 | N = 63        | • Single ascending dose study  
• Five different dose levels investigated  
• Multiple ascending dose study  
• Five different dose levels investigated | • Safety and tolerability  
• Study Completed  
• Estimated publication Q1 2015 |                                               |
## PT010 (LABA/LAMA/ICS)
### COPD development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design (B = Budesonide, G = Glycopyrronium, F = Formoterol fumarate)</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Healthy volunteers        | Phase I     | N = 84        | • ARM 1: BGF MDI 320/14.4/9.6 μg  
• ARM 2: BGF MDI 160/14.4/9.6 μg  
• ARM 3: BGF MDI 80/14.4/9.6 μg  
• ARM 4: GFF MDI 14.4/9.6 μg  
• ARM 5: Symbicort MDI 320/9 μg  
• ARM 6: Symbicort MDI 160/9 μg  
Randomized, double-blind within device, four-period, six-treatment, cross-over  
Single centre Phase 1 unit | • Overall safety  
• PK parameters AUC0-12 and Cmax | • FSI Q4 13  
• LSI Q4 13  
• Est completion Q1 14  
• Est external presentation Q2 14 (ATS) |
## RDEA3170 (URAT1)

### Gout development program

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Subjects with Gout       | Phase II NCT01927198 | N = 160       | • Arm A: Placebo  
• Arm B: RDEA3170 5 mg QD  
• Arm C: RDEA3170 10 mg QD  
• Arm D: RDEA3170 12.5 mg QD | • Efficacy at Week 12  
• FSI Q3 13  
• LSI Q4 13  
• Estimated completion Q214 |
## AZD9291 (3rd Generation EGFR TKI)
### NSCLC development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced NSCLC TKI failure with activating EGFR mutations +/- primary resistance mutation T790M</td>
<td>Phase I AURA</td>
<td>N ~ 200</td>
<td>Dose escalation study, Cohort expansion</td>
<td>Safety and tolerability</td>
<td>FSI Q1 13, Est completion Q4 14, Est external presentation Q2 14 (ASCO), Est external presentation final data Q2 15 (ASCO)</td>
</tr>
<tr>
<td>Healthy Volunteers</td>
<td>Phase I</td>
<td>N = 16</td>
<td>Arm 1: Capsule formulation, Arm 2: Solution formulation, Arm 3: Tablet formulation, Arm 4: Tablet fasted, Arm 5: Tablet fed, Ph I open label bioavailability study/food effect, 3 arm crossover</td>
<td>PK</td>
<td>FSI Q4 13, LSI Q4 13, Est completion Q2 14, Est external presentation Q2 14 (ASCO)</td>
</tr>
</tbody>
</table>
# AZD1775 (WEE-1)

## Solid tumours development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Adult Patients with Advanced Solid Tumors | Phase I | N = 200 | Dose escalation study monotherapy & combination with either gemcitabine or cisplatin  
• In part 2B of the study, MTD was 225 mg BID X 5 doses with carboplatin and 200 mg BID X 5 doses with cisplatin | Tolerability, PK/PD  
• ORR | FSI Q2 08  
• LSI Q3 13  
• Est completion Q1 14  
• Est external presentation Q2 14 |
| | NCT00648648 | | | | |
| | | | | ARM 1: carbo/paclitaxel + AZD1775 225mg  
ARM 2: carbo/paclitaxel  
Global study 9 countries | Progression Free Survival  
• Overall Survival is a secondary endpoint. | FSI Q4 11  
• LSI Q3 14  
• Est completion Q1 15  
• Est external presentation Q2 16 (ASCO) |
| p53 mutant platinum sensitive relapsed ovarian cancer | Phase II | N = 120 | | | |
| | NCT01357161 | | | | |
## AZD4547 (FGFR) Solid tumours development programme

<table>
<thead>
<tr>
<th>Patient population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Advanced solid tumours who have failed standard therapy or for whom no standard therapy exists | Phase I NCT00979134 | N = 149 | Part A: AZD4547 monotherapy in ascending multiple doses (c. 50 patients)  
Part B: AZD4547 monotherapy multiple dosing at recommended dose from Part A  
Part C: AZD4547 monotherapy in cohorts of patients whose tumours have FGFR amplification | Part A: MTD and recommended dose for Parts B and C  
Part B: Safety and tolerability  
Part C: Safety, tolerability and tumour size assessment | Parts A,B, C1  
• Presented at AACR, 2013  
Parts C2/3  
• Est external presentation Q2 14 (ASCO) |
| Advanced cancer who have failed standard therapy or for whom no standard therapy exists | Phase I NCT01213160 | N = 33 | Part A: AZD4547 monotherapy in ascending multiple doses given bd and od (c. 30 patients)  
Part B: AZD4547 monotherapy in patients whose tumours have FGFR amplification (c. 8 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 | Recruited Q1 13 |
| Female ER+ Breast cancer patients whose disease has progressed following treatment with one prior endocrine therapy | Phase IIB GLOW NCT01202591 | N = 900 | Part A: AZD4547 in ascending multiple doses in combination with 25mg exemestane  
Part B:  
• ARM 1: AZD4547 (dose from part A) + fulvestrant  
• ARM 2: Fulvestrant  
Patients with FGFR1 polysomy (30 patients) or FGFR1 amplification (60 patients) | Part A: MTD of AZD4547 in combination with 25mg exemestane in three schedules of AZD4547  
Part B Interim analysis: Tumour size analysis on 30 FGFR amplified patients  
Part B Final analysis: Progression Free Survival | Part A recruited  
Part B  
• FSI Q3 13  
Interim analysis  
• Est Q414  
Final analysis  
• Est Q4 15 |
| Advanced gastro-oesophageal cancer | Phase II SHINE NCT01457846 | N = 71 | Stratum A (FGFR2 polysomy): AZD4547 vs paclitaxel randomised 1:1 (30 to 80 patients)  
Stratum B (FGFR 2 low gene amplification: AZD4547 vs paclitaxel randomised 3:2 (25 to 80 patients)  
Stratum C (FGFR2 high gene amplification: AZD4547 vs paclitaxel randomised 3:2 (25 to 80 patients) | Progression Free Survival  
• Key Secondary: Overall survival/Tumour size | Recruitment closed after an interim analysis Q213  
• Est external presentation Q4 14 |
# AZD6094 (volitinib) (cMET)

**Oncology development programme**

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Cancer (All comers)</td>
<td>Phase I</td>
<td>N ~ 40</td>
<td>• Dose escalation study</td>
<td>• Safety and tolerability</td>
<td>• FSI Q1 12</td>
</tr>
<tr>
<td></td>
<td>NCT01773018</td>
<td></td>
<td>Conducted in Australia</td>
<td></td>
<td>• LSI Q1 14</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
<td>• Est completion Q3 14</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>• Est external presentation Q2 14 (AACR &amp; ASCO)</td>
</tr>
<tr>
<td>Advanced Cancer (All comers)</td>
<td>Phase I</td>
<td>N ~ 20</td>
<td>• Dose escalation study</td>
<td>• Safety and tolerability</td>
<td>• FSI Q2 13</td>
</tr>
<tr>
<td></td>
<td>NCT0198555</td>
<td></td>
<td>Conducted in China</td>
<td></td>
<td>• LSI Q1 14</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>• Est completion Q2 14</td>
</tr>
</tbody>
</table>
## AZD9150 (STAT3)

### Oncology development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| HCC                | Phase I     | N = 80        | • Dose-escalation and dose-expansion study  
Study conducted in Japan, Korea, Taiwan and Hong Kong | • Safety and tolerability  
• Recommended phase II dose and schedule | • FSI Q2 13  
• Est completion Q4 14  
• Est external presentation Q4 14 (EORTC) |
|                   | NCT01839604 |               |        |                  |        |
| DLBLC             | Phase I*    | N = 80        | • Dose-escalation and dose-expansion study  
Study conducted in US | • Safety and tolerability  
• Recommended phase II dose and schedule | • FSI Q1 12  
• Est completion Q1 15  
• Est external presentation Q4 14 (ASH) |

* Sponsored by ISIS
## AZD3293 (BACE)

### Alzheimer’s Disease development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of Patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Healthy Volunteers | Phase I     | N = 72        | • Active ARMS: AZD3293 single doses, ascending doses ranging from 1mg to a maximum of 1000mg  
• Comparator ARM: placebo | • AEs, labs, vital signs, ECGs  
• PK  
• PD (Aβ 40 and 42 plasma) | • Poster presentation Clinical Trial in Alzheimer’s Disease Conference Q4 13  
• Est external presentations Q1 & Q3 14 |
| Healthy volunteers and Alzheimer’s Disease Patients | Phase I     | N = 56        | • Active ARMS:  
• (Part 1) AZD3293 multiple ascending doses, starting with 5 mg  
• (Part 2) Multiple doses (12 days) of AZD3293 one to up to 3 dosage levels  
• Comparator ARM: Placebo | • AEs, labs, vital signs, ECGs  
• PK  
• PD (Aβ40 and 42 plasma and CSF) | • Est. Completion date Q1 14  
• Partial data included in Clinical Trial in Alzheimer’s Disease Conference Q4 13  
• Est external presentations Q1 & Q3 14 |
| Healthy Volunteers | Phase I     | N = 40        | • Active ARMS: Ascending AZD3293 single doses (15, 50, 150 mg planned) and multiple doses (15, 50 mg doses planned)  
• Comparator ARM: placebo | • AEs, labs, vital signs, ECGs  
• PK  
• PD (Aβ 40 and 42 plasma) | • FSI Q4 13  
• Est. Completion date Q2 14 |
| Healthy Volunteers | Phase I     | N = 61        | • Active ARMS: AZD3293 single and multiple doses open label, alone and in combination with CYP3A4 inhibitors (itraconazole, diltiazem, and midazolam) in fixed sequence design  
DDI study | • AEs, labs, vital signs, ECGs  
• PK | • FSI Q4 13  
• Est. Completion date Q1 14 |
AZD3293 (BACE)  
Alzheimer’s Disease development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Endpoints</th>
<th>Status</th>
</tr>
</thead>
</table>
| Healthy Volunteers         | Phase I     | N = 16        | • **ARMS 1 and 2:** Single AZD3293 doses in two separate tablet formulations  
• **Comparator ARM:** Single AZD3293 dose in oral solution  
1 site in US | • AEs, labs, vital signs, ECGs  
• PK | • FSI Q1 14.  
• LSO Q1 14. |
|                            | NCT02039180 |               |                                                                        |                                                                          |                         |
| Healthy Volunteers         | Phase I     | N = 52        | • **CROSSOVER:** AZD3293 (one single high dose and one single low dose), placebo, and moxifloxacin single doses  
1 site in US | • QTcF and secondary ECG variables in relation to plasma exposure of AZD3293  
• PK  
• AEs, labs, vital signs, ECG and telemetry results | • FSI Q1 14.  
• LSO Q2 14. |
|                            | NCT02040987 |               |                                                                        |                                                                          |                         |
### ATM-AVI (Aztreonam-Avibactam β- lactamase)

**Serious infections development programme**

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy volunteers</td>
<td>Phase I</td>
<td></td>
<td></td>
<td>Safety/tolerability, Pharmacokinetics (secondary)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NCT01689207</td>
<td>N = 12</td>
<td>• Randomised, double-blind, 3-part study in healthy young and elderly volunteers given Aztreonam and Avibactam alone and in combination</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>N = 54</td>
<td>• <strong>Part A:</strong> single 1 hour IV infusions</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>N = 35</td>
<td>• <strong>Part B:</strong> single IV infusion on Days 1 and 11 and multiple (every 6 hr) IV infusions on Days 2-10. Various dose regimens of Aztreonam-Avibactam are being tested.</td>
<td></td>
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<tr>
<td></td>
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<td>• <strong>Part C:</strong> multiple (every 6 hr) IV infusions Days 1-10 in healthy young and elderly volunteers</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Single center in UK</td>
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</tr>
</tbody>
</table>

• FSI Q4 12
• LSI Q4 14
• Est completion date Q1 15
• Est external presentation Q3 15 (ICAAC)
MedImmune
Early development programmes

Q1 2014
### Sifalimumab/MEDI-545 (anti-interferon α mAb)

#### SLE development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Moderate-severe SLE patients | Phase II      | N= 431        | • **Arm 1:** 200 mg IV MEDI-545 q2wks for 4 wks then monthly for 44 wks  
• **Arm 2:** 600 mg IV MEDI-545 q2wks for 4 wks then monthly for 44 wks  
• **Arm 3:** 1200 mg IV MEDI-545 q2 wks for 4 wks then monthly for 44 wks  
• **Arm 4:** placebo IV q2wks for 4 wks then monthly for 44 wks | • Proportion of subjects achieving a response in an SLE responder index at 12 months | • FSI Q2 11  
• Est completion Q2 14 |
| SLE, DM or PM patients    | Phase II      | N=260         | • 600 mg IV Medi-545  
Open label study                     | • Evaluate long-term safety and tolerability of multiple IV doses of MEDI-545 | • FSI Q3 10  
• Est completion Q1 15 |
## MEDI-546 (anti-type I IFN receptor mAb)
### SLE development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Moderate-severe SLE patients | Phase II | N = 300 | • ARM 1: 300 mg IV MEDI-546 q4wks for 48 weeks  
• ARM 2: 1000 mg IV MEDI-546 q4wks for 48 weeks  
• ARM 3: placebo IV q4wks for 48 weeks | • Response in SLE responder index at 6 months | • FSI Q1 12  
• Est completion Q2 15 |
|                         | NCT01438489 |               |                                                                        |                                                                                 |                                       |
| Moderate-severe SLE patients | Phase II | N = 240 | • ARM 1: MEDI-546, IV q4wks for 104 weeks | • Open-label extension to evaluate long-term safety and tolerability | • FSI Q1 13  
• Est completion Q1 17 |
|                         | NCT01753193 |               |                                                                        |                                                                                 |                                       |
| Japanese SLE patients   | Phase II | N = 21 | • ARM 1: Stage I: 100mg IV MEDI-546, single dose and multiple doses once every 4 wks for 48 wks  
Stage II: 300mgIV, multiple doses once every 4 wks for 104 wks  
• ARM 2: Stage I: 300mg IV MEDI-546, single dose and multiple doses once every 4 wks for 48 wks  
Stage II: 300mgIV, multiple doses once every 4 wks for 104 wks  
• ARM 3: Stage I: 1000mg IV MEDI-546, single dose and multiple doses once every 4 wks for 48 wks  
Stage II: 1000mgIV, multiple doses once every 4 wks for 104 wks | • Safety profile of MEDI-546: adverse events, vital signs, clinical laboratory assessments and ECGs | • FSI Q1 12  
• Est completion Q2 17 |
|                         | NCT01559090 |               |                                                                        |                                                                                 |                                       |
### Mavrilimumab (CAM-3001) (anti-GMCSF mAb)

#### RA development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| RA patients* with an inadequate response to DMARDs                                 | Phase II EARTH Explorer 1 | N = 280       | • ARM 1: Mavrilimumab 30 mg  
• ARM 2: Mavrilimumab 100 mg  
• ARM 3: Mavrilimumab 150 mg  
• ARM 4: Placebo                                                                 | • DAS28 response at wk12  
• ACR 20 at wk 24                                                                 | FSI Q3 12  
Est completion Q1 14                                                             |
|                                                                                   | NCT01706926                |               |                                                                      |                                                                                |                                                                        |
| RA patients* who have failed 1 or 2 anti-TNF for efficacy, intolerance or safety, OR an inadequate response to DMARDs | Phase II EARTH Explorer 2 | N = 120       | • ARM 1: Mavrilimumab 100 mg q2w  
• ARM 2: golimumab                                                                  | • ACR 20/50/70 at wk 24  
• DAS28 remission  
• Function (HAQ-DI)                                                             | FSI Q1 13  
Est completion Q2 15                                                             |
|                                                                                   | NCT01706926                |               |                                                                      |                                                                                |                                                                        |
| Eligible RA patients from Explorer 1 & 2                                         | Phase II EARTH Explorer X  | N = 400       | • ARM 1: Mavrilimumab 100 mg q2w  
Open label extension of Explorer 1 & 2                                            | • Sustained disease improvement & safety                                         | FSI Q1 13  
OLE, ongoing until regulatory filing                                              |
|                                                                                   | NCT01706926                |               |                                                                      |                                                                                |                                                                        |
## Tralokinumab (anti-IL-13 mAb)

### Asthma & IPF development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults with Uncontrolled Severe Asthma</td>
<td><strong>Phase IIb</strong>&lt;br&gt;NCT01402986</td>
<td>N = 452</td>
<td><strong>Cohort 1:</strong>&lt;br&gt;- <strong>ARM 1:</strong> Tralokinumab high dose&lt;br&gt;- <strong>ARM 2:</strong> Placebo&lt;br&gt;&lt;br&gt;<strong>Cohort 2:</strong>&lt;br&gt;- <strong>ARM 1:</strong> Tralokinumab low dose&lt;br&gt;- <strong>ARM 2:</strong> Placebo&lt;br&gt;2:1 randomisation in both cohorts&lt;br&gt;Global study – 15 countries</td>
<td>• Asthma exacerbation rate at week 52&lt;br&gt;• FSI Q4 11&lt;br&gt;• Est completion Q4 13</td>
<td></td>
</tr>
<tr>
<td>Adults with Idiopathic Pulmonary Fibrosis</td>
<td><strong>Phase II</strong>&lt;br&gt;NCT01629667</td>
<td>N = 186</td>
<td>• <strong>ARM 1:</strong> Tralokinumab high dose&lt;br&gt;- <strong>ARM 2:</strong> Tralokinumab low dose&lt;br&gt;- <strong>ARM 3:</strong> Placebo&lt;br&gt;High dose: low dose: placebo (1:1:1)&lt;br&gt;Global study – 6 countries</td>
<td>• Change from baseline in percent-predicted forced vital capacity at week 72&lt;br&gt;• FSI Q4 12&lt;br&gt;• Est completion Q2 16</td>
<td></td>
</tr>
<tr>
<td>Japanese Adults with Idiopathic Pulmonary Fibrosis</td>
<td><strong>Phase II</strong>&lt;br&gt;NCT02036580</td>
<td>N = 20</td>
<td><strong>Cohort 1:</strong>&lt;br&gt;- <strong>ARM 1:</strong> Tralokinumab high dose&lt;br&gt;- <strong>ARM 2:</strong> Placebo&lt;br&gt;&lt;br&gt;<strong>Cohort 2:</strong>&lt;br&gt;- <strong>ARM 1:</strong> Tralokinumab low dose&lt;br&gt;- <strong>ARM 2:</strong> Placebo&lt;br&gt;8:2 randomisation in both cohorts&lt;br&gt;Japan only study</td>
<td>• Safety and tolerability&lt;br&gt;• FSI Q1 14&lt;br&gt;• Est completion Q4 15</td>
<td></td>
</tr>
<tr>
<td>Patient Population</td>
<td>Phase Study</td>
<td># of patients</td>
<td>Design</td>
<td>Primary Endpoint</td>
<td>Status</td>
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<tr>
<td>Multiple sclerosis</td>
<td>Phase I</td>
<td>N = 28</td>
<td>• Single ascending dose study</td>
<td>• Safety, PK</td>
<td>• Study is recruiting</td>
</tr>
<tr>
<td></td>
<td>NCT01585766</td>
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<td></td>
<td></td>
<td>• Expected to complete recruitment Q1 14</td>
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<td></td>
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<td>• Est. Completion date Q3 14</td>
</tr>
</tbody>
</table>
# MEDI-551 (anti-CD19 mAb)

## Hematological tumors development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults with relapsed or refractory B-cell chronic lymphocytic leukemia (CLL)</td>
<td>Phase II&lt;br&gt;NCT01466153</td>
<td>N = 180</td>
<td>• ARM 1: MEDI-551 (dose-level 1) and Bendamustine&lt;br&gt;• ARM 2: MEDI-551 (dose-level 2) and Bendamustine&lt;br&gt;• ARM 3: Rituxan and Bendamustine&lt;br&gt;Open label study</td>
<td>• Evaluation of the Overall Response Rate (ORR), including Complete Response (CR) or Partial Response (PR)</td>
<td>• FSI Q1 12&lt;br&gt;• Est completion Q3 15</td>
</tr>
<tr>
<td>Adults with relapsed or refractory B-cell diffuse large B-cell lymphoma (DLBCL)</td>
<td>Phase II&lt;br&gt;NCT014533205</td>
<td>N = 170</td>
<td>• ARM 1: MEDI-551 and ICE/DHAP&lt;br&gt;• ARM 2: ICE/DHAP&lt;br&gt;Open label study</td>
<td>• Evaluation of the Overall Response Rate (ORR), including Complete Response (CR) or Partial Response (PR)</td>
<td>• FSI Q3 11&lt;br&gt;• Restart Q2 12&lt;br&gt;• Est completion Q4 19</td>
</tr>
<tr>
<td>Adults with relapsed or refractory B-cell malignancies</td>
<td>Phase I/II&lt;br&gt;NCT00983619</td>
<td>N = 91</td>
<td>• Dose-escalation study&lt;br&gt;Open label study</td>
<td>• To evaluate the MTD and efficacy</td>
<td>• FSI Q2 10&lt;br&gt;• Est completion Q1 18</td>
</tr>
<tr>
<td>Adults with relapsed or refractory B-cell malignancies</td>
<td>Phase I&lt;br&gt;NCT01957579</td>
<td>N = 18</td>
<td>• Dose-escalation study&lt;br&gt;Conducted in Japan</td>
<td>• To evaluate the MTD and efficacy</td>
<td>• FSI Q2 11&lt;br&gt;• Est completion Q2 15</td>
</tr>
<tr>
<td>Adults with Newly Diagnosed multiple myeloma</td>
<td>Phase I&lt;br&gt;NCT01861340</td>
<td>N = 15</td>
<td>• Lenalidomide, Dexamethasone and MEDI-551</td>
<td>• To explore the effect of Lenalidomide, dexamethasone and MEDI-551 on multiple myeloma cancer stem cells</td>
<td>• FSI Q3 13&lt;br&gt;• Est completion Q2 16</td>
</tr>
</tbody>
</table>
# MEDI-573 (anti-IGF Ligand)

## Breast Cancer development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary endpoint</th>
<th>Status*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with HR+ HER2-, 1st line, metastatic breast cancer taking aromatase inhibitors</td>
<td>Phase I/II</td>
<td>N = 187</td>
<td>• <strong>ARM 1:</strong> MEDI-573 and Aromatase Inhibitor&lt;br&gt;• <strong>ARM 2:</strong> Aromatase Inhibitor alone&lt;br&gt;Open label study</td>
<td>• Progression Free Survival among all patients.&lt;br&gt;• retrospective evaluation of predictive biomarker +ve subgroups (e.g. those with high tumoral IRA/IRB ratio.)</td>
<td>• FSI Q2 11&lt;br&gt;• Est completion Q3 14&lt;br&gt;• Est final study completion Q3 15</td>
</tr>
</tbody>
</table>
## MEDI4736 (anti-PD-L1 mAb)

### Solid tumours development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| NSCLC, SCCHN, HCC, pancreas, triple-negative BC, gastroesophageal, uveal melanoma, cutaneous melanoma | Phase I NCT01693562 | N = 220 | **Dose Escalation**: 5 cohorts at Q2W and 1 cohort at Q3W  
**Dose Expansion**: 9 tumor type cohorts at the Q2W MTD defined during dose escalation  
Global study – 5 countries | Safety  
Optimal biologic dose  
Secondary endpoints include PK, immunogenicity and antitumor activity | • FSI Q3 12  
• LSI Q4 14  
• Est completion Q4 15  
• Est external presentations Q2 14 of both dose escalation and dose expansion (ASCO)  
• Further potential update Q3 14 (ESMO) |
| Solid tumors (all comers) | Phase I NCT01938612 | N = 24 | **Dose Escalation**: 3 cohorts at Q2W and 1 cohort at Q3W  
This study is being conducted in Japan | Safety  
Optimal biologic dose | • FSI Q3 13  
• LSI Q4 14  
• Est completion Q3 16 |
## MEDI4736 (anti-PD-L1) + tremelimumumab (anti-CTLA-4)

### Solid tumours development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| NSCLC (Immunotx naïve and Immunotx pretreated patient cohorts) | Phase I NCT02000947 | N = 156 | • **Dose Escalation**: minimum 5 cohorts exploring various treme Q4w and MEDI4736 Q2w dose combinations  
• **Dose Expansion**: MTD for the combination in each cohort (immunotherapy-naïve patients and immunotherapy-pretreated patients)  
North American study centers | • Safety  
• Optimal biologic dose for the combination  
• Secondary endpoints include Antitumor activity, PK and immunogenicity | • FSI Q4 13  
• LSI Q3 15  
• Est completion Q2 17  
• Est external presentation of preliminary data Q2 14 (ASCO)  
• Further potential update Q3 14 (ESMO) |
| Solid tumours | Phase I NCT01975831 | N = 102 | • **Dose Escalation**: minimum 5 cohorts exploring various treme Q4w and MEDI4736 Q2w dose combinations  
• **Dose Expansion**: 6 tumor type cohorts at the MTD defined during dose escalation  
US study centers | • Safety  
• Optimal biologic dose for the combination  
• Secondary endpoints include PK, immunogenicity, tumor response by RECIST and irRC, Progression Free Survival and Overall Survival | • FSI Q4 13  
• LSI Q3 15  
• Est completion Q3 17  
• Est external presentation of preliminary data Q3 14 (ESMO) |
# MEDI4736 (anti-PD-L1 mAb) + dabrafenib/trametinib

## Melanoma development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
</table>
| Metastatic or unresectable melanoma | Phase I/II  NCT02027961 | N = 69 | Dosage Escalation:  
- **Cohort A** – dabrafenib 150mg BD/ trametinib 2mg QD/ MEDI4736 3mg/kg Q2W (Cohort A1) or 10mg/kg Q2W (Cohort A2)  
- **Cohort B** – trametinib 2mg QD/ MEDI4736 10mg/kg Q2W  
- **Cohort C** – trametinib 2mg QD for 6 wks / MEDI4736 10mg/kg Q2W starting at week 5  
- **Dose Expansion**: Each cohort will be expanded at the maximum tolerated dose (MTD) to enroll a total of 20 subjects per cohort | Safety  
- Optimal biologic dose for the combination  
- Secondary endpoints include Objective Response and Disease Control, Duration of Response, Progression-free Survival and Overall Survival | FSI Q1 14  
- LSI Q1 15  
- Est completion Q2 17 |
<p>| BRAF-mutation+ (Cohort A) |          |               |        |                  |        |
| BRAF Wild Type (Cohorts B&amp;C) |          |               |        |                  |        |</p>
<table>
<thead>
<tr>
<th>IMT-C portfolio</th>
<th>Oncology development programme</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treme-limumab (anti-CTLA-4)</td>
<td>ARM 1: Tremelimumab, ARM 2: Placebo</td>
<td>Overall survival (OS)</td>
<td>FSI Q2 13, LSI Q2 14, Est. completion date Q2 15</td>
</tr>
<tr>
<td>Patients with unresectable pleural or peritoneal malignant mesothelioma</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>NCT01843374</td>
<td>N = 180</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>MTD, safety, ORR</td>
<td>FSI Q2 13, Est. completion date Q2 18</td>
<td></td>
</tr>
<tr>
<td>NCT01862900</td>
<td>N = 40</td>
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</tr>
<tr>
<td>MEDI 6469 (anti-OX40 mAb)</td>
<td>Single dose, MEDI6469, Cyclophosphamide (CTX) and Radiation</td>
<td>MTD, safety, efficacy</td>
<td>FSI Q4 10, Est completion Q4 15</td>
</tr>
<tr>
<td>Prostate Cancer</td>
<td>NCT01303705</td>
<td>N = 37</td>
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<tr>
<td>Prostate Cancer</td>
<td>MTD, safety</td>
<td>FSI Q4 03, Completed Q2 09</td>
<td></td>
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<tr>
<td>Phase I/II</td>
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<tr>
<td>Advanced Cancers</td>
<td>MTD, safety</td>
<td></td>
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<tr>
<td>NCT01644968</td>
<td>N = 30</td>
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<tr>
<td>Advanced Cancers</td>
<td>Safety and tolerability</td>
<td></td>
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<tr>
<td>Cancer All Comers</td>
<td>Dose Escalation Study (3+3)</td>
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<tr>
<td>NCT02013804</td>
<td>N = 24</td>
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<tr>
<td>MEDI0680/AMP-514 (anti-PD-1 mAb)</td>
<td>Safety and tolerability</td>
<td>FSI Q4 13, LSI Q2 14, Est. completion date Q2 16</td>
<td></td>
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<tr>
<td>Cancer All Comers</td>
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</table>
# MEDI3617 (anti-Ang2 mAb)

## Solid Tumors development programme

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Phase Study</th>
<th># of patients</th>
<th>Design</th>
<th>Primary Endpoint</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>Solid tumors and ovarian cancer</td>
<td>Phase I</td>
<td>N = 24-42</td>
<td>MEDI3617 Dose escalation study</td>
<td>Safety and tolerability</td>
<td>Complete</td>
</tr>
<tr>
<td></td>
<td>NCT01248949</td>
<td>N = 12-24</td>
<td>MEDI3617 + bevacizumab dose escalation, administered Q3w</td>
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<tr>
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<td></td>
<td>N = 6-12</td>
<td>MEDI3617 + paclitaxel dose escalation</td>
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<tr>
<td></td>
<td></td>
<td>N = 6-12</td>
<td>MEDI3617 + carboplatin + paclitaxel dose escalation</td>
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<tr>
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<td></td>
<td>N = 12-24</td>
<td>MEDI3617 + bevacizumab dose escalation, administered Q2w</td>
<td>Safety and tolerability</td>
<td>Recruitment Complete</td>
</tr>
<tr>
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<td></td>
<td>N = 25</td>
<td>MEDI3617 single-agent expansion in ovarian cancer patients</td>
<td>Safety and tolerability</td>
<td>FSI Q4 12 LSI Q3 14</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; 20% efficacy signal</td>
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