

AstraZeneca

Clinical Programmes

Summary

3Q 2014 Results Update

The following information about ongoing AstraZeneca clinical studies in Phases I-IV has been created with selected information from clinicaltrials.gov to facilitate understanding of key aspects of our clinical programmes and is correct to the best of our knowledge as at 30 September 2014.

It includes estimated timelines with regards to study 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.



Continued momentum in late stage pipeline

Regulatory milestones

| Compound | Indication | Milestone | |
|----------------------------|--------------------------|-----------------------|----|
| <i>Lynparza (olaparib)</i> | PSR BRCAm ovarian cancer | CHMP positive opinion | ✓✓ |
| <i>Iressa</i> | ctDNA EGFRm NSCLC | EU approval | ✓✓ |
| <i>Xigduo XR</i> | Type 2 diabetes | US approval | ✓✓ |
| <i>Movantik</i> | OIC | US approval | ✓✓ |
| <i>Moventig</i> | OIC | CHMP positive opinion | ✓✓ |

Data readouts

| Compound | Indication | Milestone | |
|--------------------|-------------------|------------------------|----|
| lesinurad | gout | Ph III topline results | ✓✓ |
| CAZ AVI | clAI | Ph III topline results | ✓✓ |
| Oncology portfolio | solid tumours | Ph I/II (ESMO) | ✓✓ |
| <i>Brilinta</i> | ATLANTIC & APOLLO | Data presented (ESC) | ✓✓ |



Movements since 2Q 2014 update

| New to Phase I | New to Phase II | New to Pivotal Study | New to Registration |
|--|--|---|--|
| <p><u>NMEs (& significant combinations)</u></p> <p>AZD9291 + anti-PD-L1 or MEK or MET advanced EGFRm NSCLC</p> <p>anti-PD-L1 mAb after AZD9291 or Iressa or selumetinib+docetaxel or tremelimumab NSCLC</p> <p>anti-PD-L1 mAb + murine OX40 agonist solid tumours</p> <p>OX40 agonist (MEDI6383) solid tumours</p> <p>anti-Psi/PcrV (MEDI3902) Pseudomonas</p> <p><u>Additional indications</u> anti-PD-L1 mAb various cancers</p> | <p><u>NMEs</u></p> <p>Lynparza (olaparib) prostate cancer</p> <p>anti-PD-L1 solid tumours</p> <p>anti-CD22 recombinant immunotoxin (moxetumomab pasudotox) pALL</p> | <p><u>NMEs</u></p> <p>tralokinumab asthma</p> <p><u>Line Extensions</u></p> <p>Nexium refractory reflux esophagitis</p> <p>Nexium stress ulcer prophylaxis</p> <p>Nexium paediatrics</p> | <p><u>Other movements</u></p> <p>Movantik Approved US</p> <p>Bydureon Pen Approved EU and Launched in US</p> <p>Onglyza SAVOR-TIMI 53 Approved & Launched in EU</p> |
| Removed from Phase I | Removed from Phase II | Removed from Phase III | Removed from Registration |
| <p><u>NMEs</u></p> <p>PIM kinase inhibitor (AZD1208) haematological malignancies</p> <p>anti-CTLA-4 MAb + EGFR inhibitor (tremelimumab + Iressa)** NSCLC</p> | <p><u>NMEs</u></p> <p>inhaled TLR7 agonist (AZD8848) asthma</p> | <p><u>Line Extension</u></p> <p>Iressa IMPRESS treatment beyond progression</p> | <p>Nexium peptic ulcer bleeding*</p> |

*Completed project **ISS



A growing and accelerating late stage pipeline

Phase 1 (39 New Molecular Entities[†])

| Small molecule | Large molecule |
|--|---|
| AZD5312 Androgen prostate | MEDI0639 DLL-4 solid tumours |
| AZD6738 ATR CLL, H&N | MEDI0680 PD-1 solid tumours |
| AZD8186 PI3K β solid tumours | MEDI-565 CEA BiTE GI tumours |
| AZD9150 STAT3 haems + solids | MEDI3617 ANG-2 solid tumours |
| AZD1419 TLR9 asthma | MEDI6383 Ox40 solid tumours |
| AZD7594 Inhaled SGRM asthma, COPD | MEDI6469 mOx40 solid tumours |
| AZD7624 Inhaled p38 inhibitor COPD | MEDI4920 CD40L-Tn3 Primary Sjögren's Syndrome |
| LAS190792* MABA asthma, COPD | MEDI-551 CD19 MS |
| AZD1979 MCH obesity | MEDI5872 B7RP1 SLE |
| AZD3293 BSECDR Alzheimer's | MEDI6012 LCAT ACS |
| AZD6423 NMDA suicidal ideation | MEDI8111 Rh-Factor II trauma/bleeding |
| ATM AVI BL/BLI SBI | MEDI1814 Amyloid β Alzheimer's |
| AZD0914 GHrAR serious infection | MEDI-550 pandemic influenza virus vaccine |
| | MEDI3902 Psl/PcrV pseudomonas |
| | MEDI4893 staph alpha toxin SSI |
| | MEDI7510 RSV sF+GLA-SE RSV prevention |
| | MEDI8897 RSV Mab YTE passive RSV prophylaxis |
| | PRVV (MEDI-559) paediatric RSV vaccine |

Oncology combinations (all Phase 1)

| | |
|---|--|
| AZD9291+MEDI4736/selumetinib/volitinib EGFR + PD-L1/MEK/NSCLC | MEDI4736+dabrafenib+trematinib^Y PD-L1+BRAF+MEK melanoma |
| MEDI4736 TATTON PD-L1 after EGFR/MEK/CTLA-4 NSCLC | MEDI4736+lressa PD-L1+EGFR NSCLC |

Phase 2 (24 New Molecular Entities[†])

| Small molecule | Large molecule |
|--|---|
| AZD1775 Wee-1 ovarian, 1L NSCLC | MEDI-551 CD19 CLL, DLBCL |
| AZD2014 TORK solid tumours | MEDI-573 IGF metastatic breast cancer |
| AZD4547 FGFR solid tumours | anifrolumab IFNaR SLE |
| AZD5363 AKT breast cancer | AZD9412 Inhaled β IFN asthma, COPD |
| AZD6094 (volitinib) MET solid tumours | mavrilimumab GM-CSFR rheumatoid arthritis |
| AZD2115 MABA (dual) COPD | MEDI2070 IL-23 Crohn's |
| PT010 LABA/LAMA/ICS COPD | MEDI7183 α 4 β 7 Crohn's, ulcerative colitis |
| LAS10097 (abediterol)* LABA asthma, COPD | MEDI9929 TSLP asthma |
| RDEA3170 URAT1 gout | sifalimumab IFNa SLE |
| AZD4901 hormone modulator PCOS | |
| AZD1722 (tenapanor) NHE3 inhibitor ESRD-Pi/CKD | |
| AZD3241 MPO Multiple System Atrophy | |
| AZD5213 H3R Tourette's, neuropathic pain | |
| AZD5847 oxazolidinone TB | |
| CXL BLI/cephalosporin MRSA | |

Phase 3 / Registration (14 New Molecular Entities^{†1})

| Small molecule | Large molecule |
|--|--|
| AZD9291^Y EGFRm T790M NSCLC | MEDI4736 PD-L1 NSCLC |
| Lynparza PARP BRCA ovarian, gastric, breast | moxetumomab CD22 HCL |
| selumetinib MEK 2L KRAS ^{WT} NSCLC, uveal melanoma, DTC | tremelimumab^Y CTLA-4 mesothelioma |
| lesinurad URAT1 gout | brodalumab IL-17R psoriasis, psoriatic arthritis |
| PT003 LABA/LAMA COPD | benralizumab IL-5R severe asthma, COPD |
| PT001 LAMA COPD | tralokinumab IL-13 severe asthma |
| roxadustat (AZD9941) HIF anaemia CKD/ESRD | |
| CAZ AVI BLI/cephalosporin SBI | |

New approvals (3 New Molecular Entities[†])

| Small molecule | Large molecule |
|---|---|
| Epanova hypertriglyceridaemia | Myalept[*] lipodystrophy |
| Movantik/Moventig opioid induced constipation | |

Terminations in 2014

AZD1208 (solid tumours) in P1, AZD4721 (COPD) in P1, MEDI4893 (SSI) in Ph1, MEDI9287 (avian 'flu) in P1, AZD5069 (asthma) in P2, AZD8848 (asthma) in P2, MEDI8968 (COPD, HS) in P2

[†] Includes significant combination programs. Parallel and LCM indications that are in the same phase as the lead indication are listed in a single box for each asset. Those in earlier phases are excluded unless they are in a different TA (Exclusions: selumetinib (2L KRAS- NSCLC) in Ph2, brodalumab (asthma) in Ph2, moxetumomab (pALL) in Ph2, tralokinumab (IPF) in Ph2)

^Y Registrational P2/3 study

^Y MedImmune-sponsored study in collaboration with GlaxoSmithKline

^{*} metreleptin (Mylapet) launched in US Q2 2014

^{*} Added to the pipeline post Q3 2014 (Almirall respiratory franchise)

Pipeline information correct as of end Q3 2014

Pipeline table as of
30th September 2014



Continued strong newsflow anticipated

Data readouts

| Compound | Indication | Milestone |
|----------------|---------------------|------------------------|
| brodalumab | psoriasis | Ph III topline results |
| sifalimumab | SLE | Ph IIb (ACR) |
| mavrilimumab | RA | Ph IIb (ACR) |
| BACE (AZD3293) | Alzheimer's disease | Ph I (CTAD) |

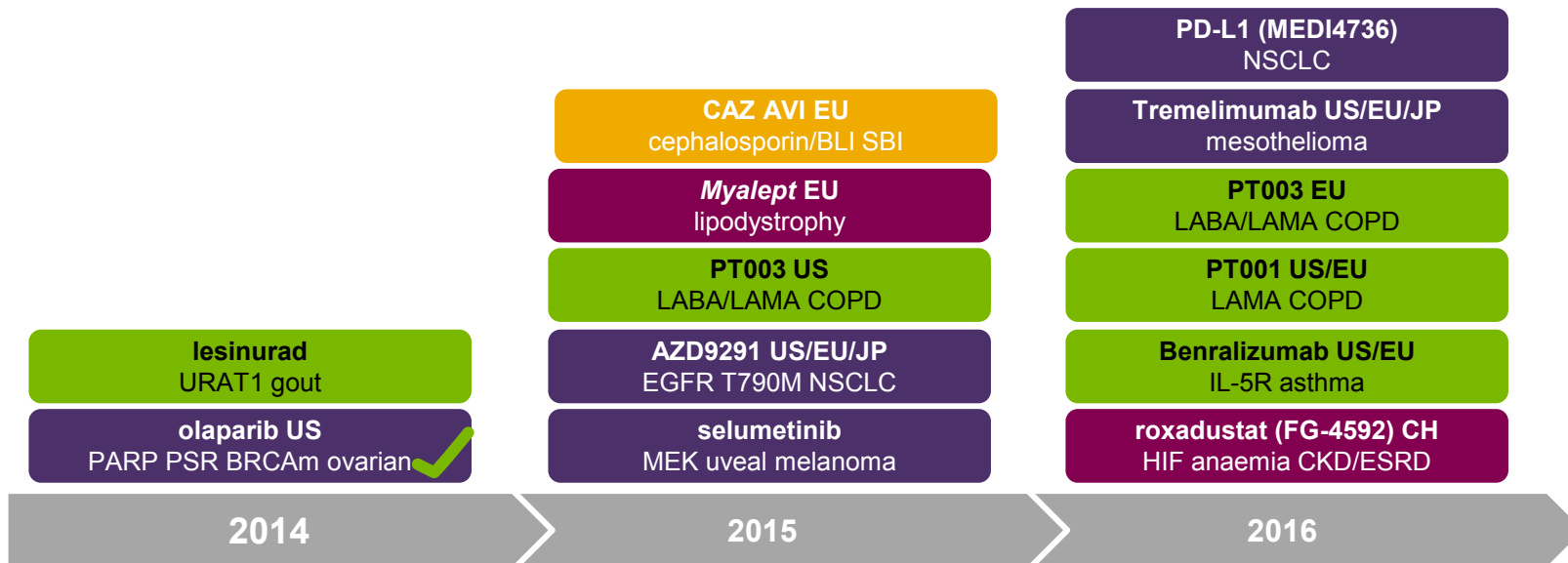
Regulatory milestones

| Compound | Indication | Potential milestones |
|--|--------------------------|--------------------------------|
| <i>Iressa</i> | EGFRm NSCLC | US filing acceptance |
| <i>Lynparza</i> (olaparib) | PSR BRCAm ovarian cancer | US approval (PDUFA 3 Jan 2015) |
| <i>Lynparza</i> (olaparib) | PSR BRCAm ovarian cancer | EU approval |
| saxagliptin/dapagliflozin FDC | type 2 diabetes | US filing |
| <i>Duaklir</i> (aclidinium/formoterol) | COPD | EU approval |
| lesinurad | gout | EU, US filing |

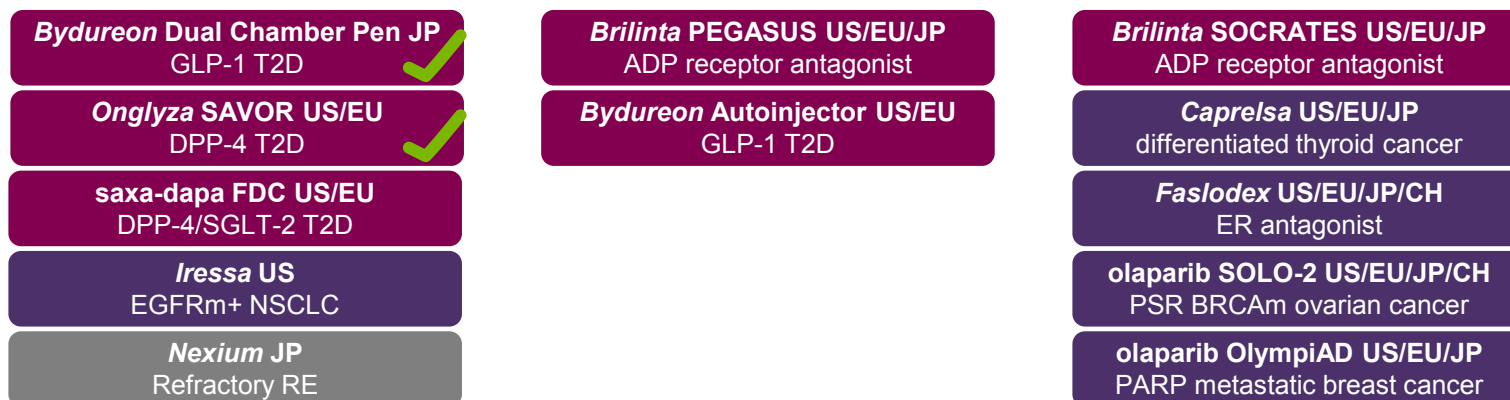


Potential NME & LE submissions 2014-16

NMEs



LEs



Oncology

RIA

CVMD

Neuroscience

Infection

GI



AstraZeneca

LE development programmes

3Q 2014 Results Update



Brilinta/Brilique (ADP receptor antagonist)

PARTHENON development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|---|---------------|---|---|--|
| Patients with prior MI | Phase III PEGASUS NCT01225562 | N = 21000 | <ul style="list-style-type: none"> • ARM 1: Ticagrelor 90 mg BiD • ARM 2: Ticagrelor 60 mg BiD • ARM 3: Placebo BiD <i>on a background of ASA</i> Global study – 31 countries | <ul style="list-style-type: none"> • Composite of CV death, non-fatal MI and non-fatal stroke | <ul style="list-style-type: none"> • FSI Q4 10 • LSI Q2 13 • Est. completion date Q1 15 • Est. external presentation Q3 15 (ESC) |
| Patients with PAD | Phase III EUCLID NCT01732822 | N = 13500 | <ul style="list-style-type: none"> • ARM 1: Ticagrelor 90 mg BiD • ARM 2: Clopidogrel 75 mg QD <i>monotherapy trial</i> Global study – 28 countries | <ul style="list-style-type: none"> • Composite of CV death, non-fatal MI and ischemic stroke | <ul style="list-style-type: none"> • FSI Q3 12 • LSI Q1 14 • Est. completion date Q3 16 • Est. external presentation 2017 |
| Patients with Stroke or TIA | Phase III SOCRATES NCT01994720 | N = 9600 | <ul style="list-style-type: none"> • ARM 1: Ticagrelor 90 mg BiD • ARM 2: ASA 100mg/day <i>monotherapy trial</i> Global study – 33 countries | <ul style="list-style-type: none"> • Composite of non-fatal stroke, non-fatal MI and all cause death | <ul style="list-style-type: none"> • FSI Q1 14 • Est. completion date Q4 15 • Est. external presentation 2016 |
| Patients with Type 2 Diabetes and Coronary Artery Disease without a previous history of MI or Stroke | Phase III THEMIS NCT01991795 | N = 17000 | <ul style="list-style-type: none"> • ARM 1: Ticagrelor 90 mg BiD • ARM 2: Placebo BiD <i>on a background of ASA if not contra indicated or not tolerated</i> Global study – approx. 40 countries | <ul style="list-style-type: none"> • Composite of CV death, non-fatal MI and non-fatal stroke | <ul style="list-style-type: none"> • FSI Q1 14 • Est. completion date Q1 17 • Est. external presentation beyond planning horizon |



Forxiga/Farxiga (SGLT-2 inhibitor)

Diabetes development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--|---------------|---|--|---|
| Type 2 diabetes mellitus with high risk for CV event | Phase III/IV DECLARE NCT01730534 | N = 17150 | <ul style="list-style-type: none"> ARM 1: Forxiga 10 mg QD + standard of care therapy QD ARM 2: Placebo + standard of care therapy for Type 2 Diabetes <p>Global study – 33 countries</p> | <ul style="list-style-type: none"> Time to first event included in the composite endpoint of CV death, MI or ischemic stroke | <ul style="list-style-type: none"> FSI Q2 13 LSI Q2 16 Est. completion date Q2 19 Est. external presentation 2020 |
| Type 1 diabetes mellitus | Phase III NCT02268214 Partnered (BMS) | N = 768 | <ul style="list-style-type: none"> Arm 1: Forxiga 5 mg QD 52 weeks + insulin Arm 2: Forxiga 10 mg QD 52 weeks + insulin Arm 3: Placebo QD 52 weeks + insulin <p>Global study – 17 countries</p> | <p><u>Primary endpoint</u></p> <ul style="list-style-type: none"> Adjusted Mean Change From Baseline in Hemoglobin A1C (HbA1c) at Week 24 <p><u>Secondary endpoints</u></p> <ul style="list-style-type: none"> Percent change in total daily insulin dose Percent change in body weight Change in the mean value of 24-hour glucose readings obtained from continuous Glucose Monitoring (CGM) <p><u>Safety:</u></p> <ul style="list-style-type: none"> Proportion of subjects with hypoglycemia events and the frequency and severity of the hypoglycemia events | <ul style="list-style-type: none"> FSI Q4 14 (planned) LSI Q1 16 Est. primary completion date Q4 16 Est. study completion date Q2 17 Estimated external presentation beyond planning horizon |



Forxiga/Farxiga (SGLT-2 inhibitor)

Diabetes development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--|---------------|---|--|--|
| Asian Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control on Insulin | Phase III NCT02096705 Partnered (BMS) | N = 260 | ARM 1: Forxiga 10 mg QD for 24 weeks + background Insulin ARM 2: Placebo QD for 24 weeks + background Insulin Asian study | • Change from baseline in HbA1c at Week 24 | • FSI Q1 14 • LSI Q2 15 • Est. Primary completion date Q4 15 |
| Japanese Patients With Type 2 Diabetes With Inadequate Glycemic Control on Insulin | Phase IV NCT02157298 | N = 224 | ARM 1: Forxiga 5mg ARM 2: Placebo Japan study | • Change from baseline in HbA1c at week16 | • FSI Q2 14 • LSI Q4 14 • Est. Primary completion date Q1 15 |



Onglyza (DPP-IV inhibitor)

Type 2 Diabetes development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--------------------------|---------------|---|--|---|
| Type 2 diabetes mellitus on insulin treatment | Phase III NCT02104804 | N = 444 | <ul style="list-style-type: none">• ARM 1: Onglyza 5 mg QD• ARM 2: Placebo QD Study in China | Primary: <ul style="list-style-type: none">• The change from baseline in HbA1C at 24 week Secondary: <ul style="list-style-type: none">• The change from baseline at 24 week in 120-minute postprandial plasma glucose (PPG) in response to a meal tolerance | <ul style="list-style-type: none">• FSI Q2 14• LSI Q4 15• Est. Primary completion date Q2 16• Est. Study completion date Q2 16 |



Saxagliptin/dapagliflozin (DPP-4/SGLT-2 inhibitors)

FDC Type 2 Diabetes development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status* |
|--------------------------|--------------------------|---------------|--|--|---|
| Type 2 Diabetes Mellitus | Phase III NCT01606007 | N = 516 | <ul style="list-style-type: none"> ARM 1: Saxa 5 mg + Met XR QD ARM 2: Dapa 10 mg + Met XR QD ARM 3: Saxa 5 mg + Dapa 10 mg + Met XR QD <p>Global study – 12 countries</p> | <p>Primary:</p> <ul style="list-style-type: none"> Mean change from baseline in HbA1C at week 24 <p>Secondary:</p> <ul style="list-style-type: none"> Mean change from baseline in 2h MTT at week 24 | <ul style="list-style-type: none"> FSI Q3 12 LSI Q2 13 Primary Completion date Q1 14 Late Breaking abstract Q2 14 (ADA) |
| Type 2 Diabetes Mellitus | Phase III NCT01619059 | N = 280 | <ul style="list-style-type: none"> ARM 1: Saxa 5mg + Dapa 10 mg + Met IR ARM 2: Placebo + Dapa 10 mg + Met IR <p>Global study – 9 countries</p> | <p>Primary:</p> <ul style="list-style-type: none"> Mean change from baseline in HbA1C at week 24 <p>Secondary:</p> <ul style="list-style-type: none"> Mean change from baseline in 2h MTT at week 24 | <ul style="list-style-type: none"> FSI Q2 12 Primary completion date Q2 14 Est. Study completion date Q1 15 Est. external presentation 2015 |
| Type 2 Diabetes Mellitus | Phase III NCT01646320 | N = 280 | <ul style="list-style-type: none"> ARM 1: Dapa 10 mg + Saxa 5 mg + Met IR ARM 2: Placebo + Saxa 5 mg + Met IR <p>Global study – 8 countries</p> | <p>Primary:</p> <ul style="list-style-type: none"> Mean change from baseline in HbA1C at week 24 <p>Secondary:</p> <ul style="list-style-type: none"> Mean change from baseline in FPG at week 24 | <ul style="list-style-type: none"> FSI Q3 12 Primary completion date Q3 14 Est. Study completion date Q1 15 Est. external presentation 2015 |



Bydureon (GLP-1 receptor antagonist)

Type 2 Diabetes development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--------------------|---|---------------|--|---|--|
| Type 2 Diabetes | Phase III DURATION-NEO 1 Partnered NCT01652716 | N = 375 | <ul style="list-style-type: none"> • ARM 1: <i>Bydureon</i> BiD SC (autoinjector) • ARM 2: <i>Bydureon</i> weekly suspension SC (autoinjector) <p>On a background of diet & exercise alone or with stable regimen of oral antidiabetes</p> <p>US only</p> | <ul style="list-style-type: none"> • Change in HbA1c from baseline at 28 weeks | <ul style="list-style-type: none"> • FSI Q1 13 • Completion date Q3 14 • External presentation Q2 14 |
| Type 2 Diabetes | Phase III DURATION-NEO 2 Partnered NCT01652729 | N = 360 | <ul style="list-style-type: none"> • ARM 1: Sitagliptin • ARM 2: <i>Bydureon</i> weekly suspension SC (autoinjector) • ARM 3: Placebo <p>On a background of diet & exercise alone or with stable regimen of oral antidiabetes</p> <p>US only</p> | <ul style="list-style-type: none"> • Change in HbA1c from baseline at 28 weeks | <ul style="list-style-type: none"> • FSI Q1 13 • Completion date Q3 14 • Est. external presentation Q2 15 |



Bydureon/exenatide (GLP-1 receptor antagonist)

Type 2 Diabetes development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--------------------|--|---------------|--|--|--|
| Type 2 Diabetes | Phase IV EXSCEL Partnered NCT01144338 | N = 14000 | <ul style="list-style-type: none"> • ARM 1: <i>Bydureon</i> once weekly 2mg SC • ARM 2: Placebo <p>On a background of standard of care medication, different degree of CV risk</p> <p>Global study</p> | <ul style="list-style-type: none"> • Time to first confirmed CV event in the primary composite CV endpoint (CV death, non-fatal MI, non-fatal stroke) | <ul style="list-style-type: none"> • FSI Q2 10 • LSI Q2 15 • Est completion date 2018 • Estimated External Presentation Beyond Planning Horizon |
| Type 2 Diabetes | Phase III DURATION 7 NCT02229383 | N = 440 | <ul style="list-style-type: none"> • ARM 1: <i>Bydureon</i> once weekly 2 mg SC + Titrated Basal Insulin • ARM 2: Placebo + Titrated Basal Insulin <p>Double-blind 1:1 randomization</p> <p>Background therapy with or without Metformin</p> <p>Global Study</p> | <ul style="list-style-type: none"> • Change in HbA1c from baseline at 28 weeks | <ul style="list-style-type: none"> • FSI Q314 • Planned LSI Q216 • Estimated completion 2016 • Estimated External Presentation Beyond Planning Horizon |
| Type 2 Diabetes | Phase III DURATION 8 NCT02229396 | N = 660 | <ul style="list-style-type: none"> • ARM 1: <i>Bydureon</i> once weekly 2 mg SC • ARM 2: Dapagliflozin 10 mg • ARM 3: <i>Bydureon</i> once weekly 2 mg SC + Dapagliflozin 10 mg <p>Double-blind 1:1:1 randomization</p> <p>Background therapy with Metformin 1500 mg/day up to 2 months prior to screening</p> <p>Global Study</p> | <ul style="list-style-type: none"> • Change in HbA1c from baseline at 28 weeks | <ul style="list-style-type: none"> • FSI Q314 • Planned LSI Q216 • Estimated completion 2017 • Estimated External Presentation Beyond Planning Horizon |



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

Hypertriglyceridaemia development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|---|---------------|--|--|---|
| Severe hypertriglyceridaemia | Phase III EVOLVE II NCT02009865 | N = 162 | <ul style="list-style-type: none"> • ARM 1: Epanova 2g QD • ARM 2: Placebo (olive oil) <p>Global study – 7 countries</p> | <ul style="list-style-type: none"> • Change in serum triglycerides over 12 weeks | <ul style="list-style-type: none"> • FSI Q4 13 • LSI Q4 14 • Est completion date Q1 15 |
| Patients with hypertriglyceridaemia and high CVD risk | Phase III STRENGTH (CVOT) NCT02104817 | N = 13,000 | <ul style="list-style-type: none"> • ARM 1: Epanova 4g QD + statin • ARM 2: Placebo (corn oil) + statin <p>Global study – 22 countries</p> | <ul style="list-style-type: none"> • Composite of MACE | <ul style="list-style-type: none"> • FSI planned to H2 14 • Est completion date H2 19 |
| Healthy Male Japanese and Caucasian subjects | Phase I SAD/MAD NCT02209766 | N = 18 | <ul style="list-style-type: none"> • ARM 1: (Japanese): Epanova 2g vs. Placebo QD • ARM 2: (Japanese): Epanova 4g vs. Placebo QD • ARM 3: (Caucasian): Epanova 4g vs. Placebo <p>Global study – 1 country</p> | <ul style="list-style-type: none"> • PK of single and multiple doses in healthy male Japanese subjects • Safety/tolerability profile | <ul style="list-style-type: none"> • FSI Q3 14 • LSI Q4 14 • Est completion date Q2 15 |
| Patients with a history of pancreatitis | Phase I NCT02189252 | N = 24 | <ul style="list-style-type: none"> • ARM 1: Epanova 4g → Lovaza 4g QD • ARM 2: Lovaza 4g → Epanova 4g QD • ARM 3: Epanova 2g → Lovaza 4g QD • ARM 4: Lovaza 4g → Epanova 2g QD <p>Global study – 2 countries</p> | <ul style="list-style-type: none"> • Plasma concentration vs. time curve (AUC_{0-τ}) [Time Frame: 0 to 24 hours (AUC₀₋₂₄)] | <ul style="list-style-type: none"> • FSI Q4 14 • LSI Q2 15 • Est completion date Q3 15 |



Myalept (recombinant leptin analogue)

Lipodystrophy development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--|---------------|---|---|---|
| Lipodystrophy | Phase III Partnered NIH /NIDDK ISS NCT01778556 | N = 72* | • ARM 1: Myalept Open label treatment protocol NIH sponsored Patients from multiple countries | • Glycaemic control • Triglycerides • Various sub-protocols | • Ongoing • Est. Completion date Q3 15 |
| Lipodystrophy with associated diabetes and/or hyper-triglyceridaemia | Phase III FHA101 Partnered BMS NCT00677313 | N = 28* | • ARM 1: Myalept Open label treatment protocol | • Glycaemic control • Triglycerides | • Ongoing • Est. Completion date Q4 14 |

* Relates to data-cut for BLA submission: studies are ongoing



Iressa (EGFR TKI)

EGFRm NSCLC development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|-----------------------------------|---------------|--|---|---|
| NSCLC (Escalation phase) EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase) | Phase I NCT02088112 | N = 47 | Escalation phase Standard 3+3 design with 28 days DLT period • Gefitinib (QD) + MEDI4736 IV Expansion phase • Gefitinib (QD) + MEDI4736 IV recommended dose Study to be conducted in US and Korea | <ul style="list-style-type: none">• Safety• Optimal biologic dose for the combination • Secondary endpoints include tumour response, Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics | <ul style="list-style-type: none">• FSI Q2 14• LSI Q1 15• Est completion date Q4 17• Estimated external presentation beyond planning horizon |



Faslodex (oestrogen receptor antagonist)

Breast cancer development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|---|---------------|---|---|---|
| Postmenopausal women with HR+ locally advanced or metastatic breast cancer, who have not previously been treated with any hormonal therapy (1 st -line) | Phase III FALCON NCT01602380 | N ~450 | <ul style="list-style-type: none"> ARM 1: Faslodex 500 mg monthly IM + an additional dose on d14 (+ oral placebo) ARM 2: Arimidex 1 mg (+ placebo injection) <p>Global study – 21 countries</p> | <ul style="list-style-type: none"> Progression Free Survival (PFS) Overall Survival is a secondary endpoint | <ul style="list-style-type: none"> FSI Q4 12 LSI Q3 14 Est primary completion date Q2 16 Est. external presentation 2016 |
| Chinese, postmenopausal women with HR+ advanced breast cancer, progressing or relapsing after previous endocrine therapy (2 nd -line) | Phase III NCT01300351 | N = 221 | <ul style="list-style-type: none"> ARM 1: Faslodex 500 mg monthly IM + an additional dose on day 14 ARM 2: Faslodex 250 mg monthly IM <p>China study</p> | <ul style="list-style-type: none"> Progression Free Survival | <ul style="list-style-type: none"> FSI Q1 11 LSI Q4 13 Primary Completion Date Q2 14 External presentation Q4 14 at the San Antonio Breast Cancer Symposium |



Thyroid cancer development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|---------------------------|---------------|--|---|--|
| Differentiated thyroid cancer refractory or unsuitable for radioiodine therapy | Phase III NCT01876784 | N = 227 | <ul style="list-style-type: none"> • ARM 1: Vandetanib 300 mg oral dose QD • ARM 2: Placebo <p>Global study – 12 countries</p> | <ul style="list-style-type: none"> • Progression Free Survival | <ul style="list-style-type: none"> • FSI Q3 13 • LSI Q4 14 • Est completion date Q2 17 • Est external presentation Q4 17 |
| Unresectable locally advanced or metastatic medullary thyroid carcinoma | Phase I/II NCT01661179 | N = 10 | <ul style="list-style-type: none"> • ARM 1: Vandetanib 300mg oral dose QD <p>Japanese patients</p> | <ul style="list-style-type: none"> • Frequency and severity of adverse events • Secondary end point objective response rate | <ul style="list-style-type: none"> • FSI Q4 12 • LSI Q2 13 • Est completion date Q3 14 |



Symbicort (ICS/LABA)

Mild asthma development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|---------------------------------|---------------|--|--|--|
| Asthma patients GINA 2 | Phase III SYGMA1 NCT02149199 | N = 3750 | <ul style="list-style-type: none"> ARM 1: Symbicort Turbuhaler 160/4.5 µg 'as needed' + Placebo Pulmicort Turbuhaler 200 µg bid ARM 2: Pulmicort 200 µg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler 'as needed' ARM 3: terbutaline Turbuhaler 0.4 mg 'as needed' + placebo Pulmicort 200 µg Turbuhaler bid <p>Global study – 19 countries</p> | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> FSI Q3 14 LSI Q3 15 Est. completion date Q4 16 Est. external presentation beyond planning horizon |
| Patients in need of GINA step 2 treatment | Phase III SYGMA2 NCT02224157 | N = 4114* | <ul style="list-style-type: none"> ARM 1: Symbicort Turbuhaler 160/4.5 µg 'as needed' + Placebo Pulmicort Turbuhaler 200 µg bid ARM 2: Pulmicort 200 µg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler 'as needed' <p>Global study – 25 countries</p> | <ul style="list-style-type: none"> Annual severe asthma exacerbation rate Time to first severe asthma exacerbation Average change from baseline in pre-dose FEV1 Time to study specific asthma related discontinuation | <ul style="list-style-type: none"> FSI Q4 2014 LSI Q4 2015 Est. completion date Q1 17 Est. external presentation beyond planning horizon |



Serious infections development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--|---|---|--|--|
| Patients with complicated skin and soft tissue infections (cSSTI) | Phase III COVERS NCT01499277 | N = 765 (801 <i>actually screened</i>) | <ul style="list-style-type: none"> • ARM 1: Ceftaroline fosamil 600 mg q 8 hrs • ARM 2: Vancomycin plus aztreonam | <ul style="list-style-type: none"> • NI in Clinical Cure rate at the Test of Cure (TOC) visit in both the modified Intent-To-Treat (MIIT) and the Clinically Evaluable (CE) analysis sets • Secondary endpoints include clinical response at End of Treatment (EOT) visit and microbiological response at TOC and EOT | <ul style="list-style-type: none"> • FSI Q2 12 • LSI Q2 14 • Completion Q2 14 • Ext presentation Q2 15 |
| Patients with complicated skin and soft tissue infections (cSSTI) | Phase III COVERS MRSA Expansion NCT02202135 | N = 60 | <ul style="list-style-type: none"> • ARM 1: Ceftaroline fosamil 600 mg q 8 hrs • ARM 2: Vancomycin plus aztreonam | <ul style="list-style-type: none"> • Assess clinical Cure rate at the Test of Cure (TOC) visit in both the modified Intent-To-Treat (MIIT) and the Clinically Evaluable (CE) analysis sets • Secondary endpoints include clinical response at End of Treatment (EOT) visit and microbiological response at TOC and EOT | <ul style="list-style-type: none"> • FSI Q2 14 • LSI Q3 15 • Est completion Q3 15 |
| Patients with Community-Acquired Pneumonia (CAP) in Asia | Phase III CAP NCT01371838 | N = 692 (848 <i>actually screened</i>) | <ul style="list-style-type: none"> • ARM 1: Ceftaroline fosamil 600 mg q 12 hrs • ARM 2: Ceftriaxone 2 g q 24 hrs | <ul style="list-style-type: none"> • NI in Clinical Cure rate at the Test of Cure (TOC) visit in Clinically Evaluable (CE) population • Secondary endpoints include clinical response at End of Treatment (EOT) visit and microbiological response at EOT | <ul style="list-style-type: none"> • FSI Q4 11 • LSI Q2 13 • Completion Q2 13 • Ext presentation Q2 14 |



FluMist Quadrivalent

Phase III development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--------------------|--------------------------|---------------|---|---|---|
| Healthy children | Phase III NCT02269475 | N = 1008 | <ul style="list-style-type: none"> • ARM 1: One or two doses of MEDI3250 • ARM 2: Placebo <p>Nasal administration</p> <p>Japan only</p> | <ul style="list-style-type: none"> • Efficacy • Safety and tolerability | <ul style="list-style-type: none"> • FSI Q4 14 • LSI Q4 14 • Est completion Q1 15 • Est external presentation Q4 15 |
| Healthy children | Phase III NCT02269488 | N =100 | <ul style="list-style-type: none"> • ARM 1: One or two doses of MEDI3250 <p>Nasal administration</p> <p>Japan only</p> | <ul style="list-style-type: none"> • Safety and tolerability | <ul style="list-style-type: none"> • FSI Q4 14 • LSI Q4 14 • Est completion Q2 15 • Est external presentation Q4 15 |



Gastrointestinal

Phase III development programmes

| Compound | Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|-------------|--|--------------------------------------|---------------|---|---|---|
| Nexium | Refractory RE | Phase III Rose NCT01669811 | N = 280 | <ul style="list-style-type: none"> • ARM 1: Nexium 20 mg BiD • ARM 2: Nexium 20 mg QD Japan-only study | <ul style="list-style-type: none"> • Healing of refractory RE | <ul style="list-style-type: none"> • FSI Q3 2012 • LSI Q1 2014 • Completion date Q2 2014 • Targeted as late breaking abstract at DDW May 2015 |
| Nexium | Seriously ill patients (Stress Ulcer Prophylaxis, SUP) | Phase III NCT02157376 | N=300 | <ul style="list-style-type: none"> • ARM 1: Nexium 30 min intermittent infusions given for max. 14 days • ARM 2: Cimetidine(Tagamet) 30 min bolus infusion + continuous infusion for max. 14 days China-only study | <ul style="list-style-type: none"> • Proportion of patients with upper GI bleeding | <ul style="list-style-type: none"> • FSI Q3 14 • LSI Q3 16 • Est completion date Q3 16 • Est external presentation 18 |
| Entocort | Crohn's disease (mild to moderate) | Phase III NCT01514240 | N = 110 | <ul style="list-style-type: none"> • ARM 1: Entocort 9 mg QD • ARM 2: Mesalazine 1 g TD Japan-only study | <ul style="list-style-type: none"> • Remission defined by a CDAI score of ≤ 150 | <ul style="list-style-type: none"> • FSI Q1 12 • LSI Q2 14 • Completion date Q3 14 • Est external presentation 16 |
| Linaclotide | IBS-C | Phase III NCT01880424 | N = 800 | <ul style="list-style-type: none"> • ARM 1: Linaclotide 290μg QD • ARM 2: placebo Participating countries China, Australia, New Zealand, USA and Canada | <ul style="list-style-type: none"> • 12-week abdominal pain/abdominal discomfort response • 12-week IBS degree of relief response | <ul style="list-style-type: none"> • FSI Q3 13 • LSI Q1 15 • Est completion date Q2 15 • Est external presentation 16 |

AstraZeneca

Late stage development programmes

3Q 2014 Results Update

Roxadustat (HIF-PHI)

Phase III CKD programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|---|---------------|--|------------------------|---|
| Anaemia in Chronic Kidney Disease Patients Not Receiving Dialysis | Phase III Andes NCT01750190 | N = 450-600 | <ul style="list-style-type: none"> • ARM 1: Roxadustat • ARM 2: Placebo Global study – 16 countries | • Haemoglobin response | <ul style="list-style-type: none"> • Sponsored by FibroGen • FSI Q4 12 • Est completion Q1 16 |
| | Phase III Alps NCT01887600 | N = 600 | <ul style="list-style-type: none"> • ARM 1: Roxadustat • ARM 2: Placebo Global study – 14 countries | • Haemoglobin response | <ul style="list-style-type: none"> • Sponsored by Astellas • FSI Q2 13 • Est completion Q2 16 |
| | Phase III Dolomites NCT02021318 | N = 570 | <ul style="list-style-type: none"> • ARM 1: Roxadustat • ARM 2: Darbeoetin alfa Global study –17 countries | • Haemoglobin response | <ul style="list-style-type: none"> • Sponsored by Astellas • FSI Q1 14 • Est completion Q3 17 |
| | Phase III Olympus NCT02174627 | N = 2600 | <ul style="list-style-type: none"> • ARM 1: Roxadustat • ARM 2: Placebo Global study – 24 countries | • MACE | <ul style="list-style-type: none"> • Sponsored by AstraZeneca • FSI Q2 14 • Est completion Q1 17 |
| Anaemia in CKD in Patients Receiving Dialysis | Phase III Rockies NCT02174731 | N = 1425 | <ul style="list-style-type: none"> • ARM 1: Roxadustat • ARM 2: Epoetin alfa Global study – 22 countries | • MACE | <ul style="list-style-type: none"> • Sponsored by AstraZeneca • FSI Q2 14 • Est completion Q1 17 |
| Anaemia in Newly Initiated Dialysis Patients | Phase III Himalayas NCT02052310 | N = 750 | <ul style="list-style-type: none"> • ARM 1: Roxadustat • ARM 2: Epoetin alfa Global study – 21 countries | • Haemoglobin response | <ul style="list-style-type: none"> • Sponsored by FibroGen • FSI Q4 13 • Est completion Q2 16 |



Lynparza (PARP inhibitor)

Solid tumours development programmes

| Patient Population | Phase Study | # of patients | Design | Primary Endpoint | Status |
|---|---------------------------------|---------------|--|--|--|
| PSR BRCAm ovarian cancer | Phase III SOLO-2 NCT01874353 | N = 264 | <ul style="list-style-type: none"> ARM 1: Lynparza tablets 300 mg BiD as maintenance therapy until progression ARM 2: placebo tablets BiD <p>Global study – 16 countries</p> | <ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint. | <ul style="list-style-type: none"> FSI Q3 13 LSI Q4 14 Primary analysis planned Q3 15 Primary presentation Q2 16 |
| 1 st line maintenance BRCAm ovarian cancer | Phase III SOLO-1 NCT01844986 | N = 344 | <ul style="list-style-type: none"> ARM 1: Lynparza tablets 300 mg BiD maintenance therapy for 2 years or until disease progression ARM 2: placebo <p>Global study – 15 countries</p> | <ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint. | <ul style="list-style-type: none"> FSI Q3 13 LSI Q1 15 Primary analysis planned Q3 16 Primary presentation Q2 17 |
| 2 nd line gastric cancer (all patients with a co-primary sub population) | Phase III GOLD NCT01924533 | N = 500 | <ul style="list-style-type: none"> ARM 1: paclitaxel + Lynparza until progression ARM 2: paclitaxel + placebo <p>Lynparza dose 100mg BiD throughout paclitaxel dose cycle & 300 mg BiD post cycle</p> <p>The study will be conducted in Korea, China, Taiwan and Japan</p> | <ul style="list-style-type: none"> Overall Survival | <ul style="list-style-type: none"> FSI Q3 13 LSI Q3 15 Est completion date Q3 16 Est external presentation Q3 17 |



Lynparza (PARP inhibitor) continued...

Solid tumours development programmes

| Patient Population | Phase Study | # of patients | Design | Primary Endpoint | Status |
|--|--|---------------|---|---|---|
| BRCAm metastatic breast cancer | Phase III OlympiAD NCT02000622 | N = 310 | <ul style="list-style-type: none"> ARM 1: Lynparza 300 mg BiD, continuous to progression ARM 2: Physician's choice: Capecitabine 2500 mg/m² x 14 q 21 Vinorelbine 30 mg/m² d 1, 8 q 21 Eribulin 1.4 mg/m² d 1, 8 q 21 to progression | <ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint | <ul style="list-style-type: none"> FSI Q2 14 LSI Q4 15 Est completion date Q2 16 External Presentation Q2 17 |
| BRCAm adjuvant breast cancer | Phase III OlympiA NCT02032823 | N = 1500 | <ul style="list-style-type: none"> ARM 1: Lynparza 300 mg BiD 12 month duration ARM 2: Placebo 12 month duration <p>Global study partnership with BIG and NCI/NRG</p> | <ul style="list-style-type: none"> IDFS Secondary Endpoint DFS and OS | <ul style="list-style-type: none"> FSI Q2 14 LSI Q1 18 Est primary analysis Q1 20 |
| Pancreas gBRCA | Phase III POLO NCT02184195 | N = 145 | <ul style="list-style-type: none"> ARM 1: Lynparza tablets 300 mg twice daily as maintenance therapy until progression. ARM 2: placebo tablets BiD <p>Global Study approx 10 countries</p> | <ul style="list-style-type: none"> Primary Endpoint PFS OS secondary endpoint | <ul style="list-style-type: none"> FSI Q4 2014 LSI Q4 2015 Results Q1 2016 Estimated external presentation: Q2 16 |
| Metastatic Castration Resistant Prostate CA | Phase II NCT01972217 | N = 170 | <ul style="list-style-type: none"> ARM 1: Lynparza 200 or 300mg BiD + Abiraterone ARM 2: Placebo + Abiraterone <p>Global study</p> | <ul style="list-style-type: none"> Radiologic Progression Free Survival | <ul style="list-style-type: none"> FSI Q2 14 LSI Q3 2017 Est completion date Q316 |



Selumetinib (AZD6244, ARRY142886) (MEK-inhibitor)

Solid tumours development programmes

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--|---------------|--|--|--|
| 2nd Line KRAS M positive NSCLC | Phase III SELECT-1 NCT01933932 | N = 634 | <ul style="list-style-type: none"> ARM 1: Selumetinib 75mg BiD + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle ARM 2: Placebo BiD + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle <p>Global study – 26 countries</p> | <ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint. | <ul style="list-style-type: none"> FSI Q3 13 LSI Q1 16 Est completion date Q1 17 Estimated external presentation beyond planning horizon |
| 2nd Line KRAS M negative NSCLC | Phase II SELECT-2 NCT01750281 | N = 265 | <ul style="list-style-type: none"> ARM 1: Selumetinib 75mg BiD + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle ARM 2: Selumetinib 75mg BiD + docetaxel 60 mg/m² IV on day 1 of each 21 day cycle ARM 3: Placebo BiD + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle <p>Global study – 7 countries</p> | <ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint. | <ul style="list-style-type: none"> FSI Q4 12 LSI Q4 14 Est completion date Q4 15 Est external presentation 2015 |
| Metastatic Uveal Melanoma | Phase III SUMIT NCT01974752 | N = 128 | <ul style="list-style-type: none"> ARM 1: Selumetinib 75 mg BiD + dacarbazine 1000 mg/m² day 1 of every 21 day cycle ARM 2: Placebo BiD + dacarbazine 1000 mg/m² day 1 of every 21 day cycle <p>3:1 Randomisation Global study – 10 countries</p> | <ul style="list-style-type: none"> Progression Free Survival | <ul style="list-style-type: none"> FSI Q2 14 LSI Q1 15 Est completion date Q2 15 Est external presentation 2015 |
| Differentiated Thyroid Cancer | Phase III ASTRA NCT01843062 | N = 304 | <ul style="list-style-type: none"> ARM 1: Selumetinib 75mg BiD 5 weeks duration + RAI 100mCi^a ARM 2: Placebo BiD 5 weeks duration + RAI 100mCi^a <p>Global study – 8 countries</p> <p>^a Single dose of 100mCi ¹³¹I administered following 4 weeks of selumetinib (or placebo).</p> | <ul style="list-style-type: none"> Complete remission (CR) rate at 18 months post-RAI Clinical remission rate at 18 m post RAI (per SoC) | <ul style="list-style-type: none"> FSI Q3 13 LSI Q2 15 Est completion date Q117 Estimated external presentation beyond planning horizon |

AZD9291 (Highly selective, irreversible EGFR TKI)

NSCLC development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|------------------------------------|---------------|---|--|---|
| Advanced EGFRm NSCLC TKI failure + /- primary resistance mutation T790M | Phase I/II AURA NCT01802632 | N ~ 500 | <ul style="list-style-type: none"> Dose escalation study Ph II Extension cohort 80mg QD | <ul style="list-style-type: none"> Safety and tolerability ORR PFS and OS secondary endpoints | <ul style="list-style-type: none"> FSI Q1 13 Enrolment complete Next external presentation; final data Q2 15 |
| Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M | Phase II AURA2 NCT02094261 | N = 175 | <ul style="list-style-type: none"> ARM 1: AZD9291 80 mg QD <p>Global study – 5 countries</p> | <ul style="list-style-type: none"> ORR PFS and OS secondary endpoints | <ul style="list-style-type: none"> FSI Q2 14 Enrolment complete Est external presentation: ASCO 2015 |
| Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M | Phase III AURA3 NCT02151981 | N= 610 | <ul style="list-style-type: none"> ARM 1: AZD9291 80mg QD ARM2: pemetrexed 500mg/m2 + carboplatin AUC5 or pemetrexed 500mg/m2 + cisplatin 75mg/m2 (2:1 randomization) | <ul style="list-style-type: none"> PFS OS and QoL as secondary endpoints | <ul style="list-style-type: none"> FSI Q3 2014 Est completion Q2 16 Est external presentation: TBD |
| Advanced EGFRm NSCLC 1L | Phase III FLAURA Not yet posted | N=720 | <ul style="list-style-type: none"> ARM1: AZD9291 80mg ARM2: erlotinib 150mg or gefitinib 500mg (dealers choice); 1:1 randomisation | <ul style="list-style-type: none"> PFS OS and QoL as secondary endpoints | <ul style="list-style-type: none"> FSI Q4 2014 Est completion 2017 Est external presentation: TBD |
| Advanced EGFRm NSCLC TKI failure | Phase Ib TATTON NCT02143466 | N~90 | <ul style="list-style-type: none"> ARM 1: AZD9291 + MEDI4736 ARM 2: AZD9291 + AZD6094 ARM 3: AZD9291 + selumetinib | <ul style="list-style-type: none"> Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity | <ul style="list-style-type: none"> FSI Q3 2014 Est completion Q3 15 Est external presentation: TBD |



Anti-PD-L1 (MEDI4736)

Solid tumours development programmes

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|---|---------------|---|---|---|
| Stage IIIB-IV NSCLC patients PD-L1+ve Patients | Phase II Atlantic NCT02087423 | N = 188 | <ul style="list-style-type: none"> ARM 1: MEDI4736 IV Q2W (EFGR/ALK WT) ARM 2: MEDI4736 IV Q2W (EFGR/ALK M+) Global study – 18 countries | <ul style="list-style-type: none"> Objective Response Rate Secondary endpoints include duration of response, progression free survival and overall survival | <ul style="list-style-type: none"> FSI Q1 14 LSI Q1 15 Est completion date Q1 16 Est external presentation: 2016 |
| Unresectable Stage III NSCLC patients following platinum-based concurrent chemo-radiation therapy | Phase III Pacific NCT02125461 | N = 702 | <ul style="list-style-type: none"> ARM 1: MEDI4736 IV Q2W ARM 2: placebo Global study | <ul style="list-style-type: none"> Progression Free Survival (PFS) Overall Survival (OS) | <ul style="list-style-type: none"> FSI Q2 14 LSI Q1 16 Est completion date Q2 17 Est external presentation beyond planning horizon |
| Stage IIIB-IV NSCLC patients who have not be tested positive for EGFR/Alk mutation | Phase III Arctic Not yet posted | N =900 | <p>Substudy A</p> <ul style="list-style-type: none"> ARM 1: MEDI4736 IV Q2W (PD-L1+ patients) ARM 2: Standard of Care <p>Substudy B</p> <ul style="list-style-type: none"> ARM 3: MEDI4736+tremelimumab (PD-L1 –ve patients) ARM 4: Standard of Care ARM 5: tremelimumab ARM 6: MEDI4736 Dose and Schedule for Combination Arm under discussion | <ul style="list-style-type: none"> Progression Free Survival (PFS) Overall Survival (OS) | <p><u>Monotherapy arm</u></p> <ul style="list-style-type: none"> FSI planned Q4 14 LSI Q116 Est completion date Q416 <p><u>Combination therapy</u></p> <ul style="list-style-type: none"> FSI planned Q4 14 LSI Q116 Est completion date Q117 <ul style="list-style-type: none"> Est external presentation beyond planning horizon |

Anti-PD-L1 (MEDI4736) continued...

Solid tumours development programmes

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--|-------------------------|--|--|---|
| Stage IIIB-IV NSCLC patients Biomarker-Targeted Second-Line Therapy | Phase II/III Lung Master Protocol Partnered with NCI and SWOG NCT02154490 | N = 400 (4736 arm only) | 5-Arm study based on biomarker expression <ul style="list-style-type: none"> • ARM 1: MEDI4736 Unmatched biomarker IVQ2W • ARM 2: AZD4547 (FGFR inhibitor) • ARM 3: CDK4/6 inhibitor • ARM 4: PI3K Inhibitor • ARM 5: HGFR Inhibitor | <ul style="list-style-type: none"> • Progression Free Survival (PFS) • Overall Survival (OS) | <ul style="list-style-type: none"> • FSI Q2 14 • LSI (Phase II Q3 15) • Est completion date Q1 17 • Est external presentation beyond planning horizon |
| Stage IIIB-IV NSCLC patients | Phase I/II Sequencing Study NCT02179671 | N = 72 | <ul style="list-style-type: none"> • ARM 1: Iressa initially then switch to MEDI4736 IVQ2W • ARM 2: AZD9291 then switch to MEDI4736 • ARM 3: Selumetinib + Docetaxel then switch to MEDI4736 • ARM 4: tremelimumab then switch to MEDI4736 | <ul style="list-style-type: none"> • Complete Response Rate • ORR, Disease Control Rate | <ul style="list-style-type: none"> • FSI Q3 14 • LSI Q2 15 • Est completion date Q3 16 • Est external presentation: 2016 |
| SCCHN | Phase II NCT02207530 | N= 112 | <ul style="list-style-type: none"> • ARM 1: MEDI4736 IVQ2W | <ul style="list-style-type: none"> • ORR | <ul style="list-style-type: none"> • FSI planned Q4 14 • LSI Q2 15 • Est completion date Q4 15 • Est external presentation beyond planning horizon |



Anti-PD-L1 (MEDI4736) continued...

Solid tumours development programmes

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---------------------------------------|--|---------------|--|---|--|
| Solid tumors (all comers) | Phase I NCT01938612 | N = 24 | <ul style="list-style-type: none"> • Dose Escalation: 3 cohorts at Q2W and 1 cohort at Q3W <p>This study is being conducted in Japan</p> | <ul style="list-style-type: none"> • Safety • Optimal biologic dose | <ul style="list-style-type: none"> • FSI Q3 13 • LSI Q4 14 • Est completion Q2 16 |
| Stage IB (≥4cm) – IIIA Resected NSCLC | Phase III NCT02273375 Partnered: Non-Sponsored Study Run By NCIC | N= 1100 | <ul style="list-style-type: none"> • ARM 1: MEDI4736 IV Q2W • ARM 2: placebo | <ul style="list-style-type: none"> • Disease free survival (DFS) in PD-L1+ patients • Secondary endpoints include overall survival (OS) in both PD-L1+ and non-selected patients, safety, and QoL assessments | <ul style="list-style-type: none"> • FSI Planned Q4 14 • LSI Q1 18 • Est completion date beyond planning horizon • Est external presentation beyond planning horizon |



Anti-CTLA-4 (tremelimumab)

Mesothelioma development programme

| Patient | Population | Phase Study | # of Patients | Design | Endpoint(s) | Status |
|---------|---|-------------------------|---------------|---|---|---|
| | Patients with unresectable pleural or peritoneal malignant mesothelioma | Phase II NCT01843374 | N = 564 | <ul style="list-style-type: none">• ARM 1: Tremelimumab IV• ARM 2: Placebo | <ul style="list-style-type: none">• Overall survival (OS) | <ul style="list-style-type: none">• FSI Q2 13• LSI Q1 15• Est completion date Q2 16 |



Moxetumomab Pasudotox (anti-CD22)

Haematological malignancies development programmes

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--------------------------|---------------|---|---|---|
| Adults with relapsed refractory HCL | Phase I NCT00586924 | N = 49 | • Open Label dose escalation study | • MTD and efficacy | • FSI Q2 07 • LSI Q1 14 • Est. completion Q1 15 |
| Adults with relapsed or refractory HCL | Phase III NCT01829711 | N = 77 | • Multicenter, Single-Arm, Open label study | • Primary: Rate of durable CR: CR maintained for > 180 days • Efficacy: CR rate, ORR, Duration of CR and ORR, time to response (TTR), PFS • Safety and tolerability • PK and immunogenicity | • FSI Q1 13 • Est completion Q3 16 |
| Children, Adolescents and Young Adults with refractory ALL or NHL | Phase I NCT00659425 | N = 55 | • Multicenter, Dose Escalation Study | • To estimate MTCD • To characterize tolerability and safety profile • To study clinical PK • To observe anti-tumor activity | • FSI Q3 08 • LSI Q2 14 • Est. Completion Q4 15 |
| Pediatrics with relapsed or refractory pALL or lymphoblastic lymphoma of B-cell origin | Phase II NCT02227108 | N = 76 | • Multicenter, Single-arm, Open label study | • Primary: CRc rate (CR + CRi) • Efficacy: MRD negative CRc rate, ORR (CR, CRi, PR), rate of eligibility for stem cell transplant, DCOR, DOR, PFS and OS • Safety and tolerability • Evaluate PK | • FSI Q3 14 • LSI Q2 16 • Est Completion Q4 17 |



Anti-IL-5R α (benralizumab)

Asthma development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--|----------------------------|---|---|--|
| Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA \pm chronic OCS Age 12 – 75yrs | Phase III CALIMA NCT01914757 | N = 1026 HD + up to 250 MD | <ul style="list-style-type: none"> • ARM 1: 30 mg Q8w SC • ARM 2: 30 mg Q4w SC • ARM 3: Placebo SC 56-week study Global study – 11 countries | <ul style="list-style-type: none"> • Annual Asthma Exacerbation Rate • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalization visits, PK, and IM | <ul style="list-style-type: none"> • FSI Q4 13 • Est completion date Q2 16 |
| Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA \pm chronic OCS Age 12 – 75 yrs | Phase III SIROCCO NCT01928771 | N = 1134 | <ul style="list-style-type: none"> • ARM 1: 30 mg Q8w SC • ARM 2: 30 mg Q4w SC • ARM 3: Placebo SC 48-week study Global study – 17 countries | <ul style="list-style-type: none"> • Annual Asthma Exacerbation Rate • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalization visits, PK, and IM | <ul style="list-style-type: none"> • FSI Q4 13 • Est completion date Q1 16 |
| Severe asthma, inadequately controlled on high dose inhaled corticosteroid plus long-acting β 2 agonist and chronic oral corticosteroid therapy Age 18 – 75 yrs | Phase III ZONDA NCT02075255 | N = 120 | <ul style="list-style-type: none"> • ARM 1: 30 mg Q8w SC • ARM 2: 30 mg Q4w SC • ARM 3: Placebo SC 46-week study Global study – 7 countries | <ul style="list-style-type: none"> • Reduction of Oral Corticosteroid dose | <ul style="list-style-type: none"> • FSI Q3 14 • Est completion date Q1 16 |



Anti-IL-5R α (benralizumab)

COPD development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--|---------------|---|---|--|
| Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD) with Exacerbation History | Phase III TERRANOVA NCT02155660 | N = 2324 | <ul style="list-style-type: none"> • ARM 1: 10 mg Q8w SC • ARM 2: 30 mg Q4w SC • ARM 3: 100 mg Q8w SC • ARM 4: Placebo SC 48-week study Global study – 15 countries | <ul style="list-style-type: none"> • Rate of COPD Exacerbation | <ul style="list-style-type: none"> • FSI Q3 14 • Est completion date Q4 17 |
| Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD) with Exacerbation History | Phase III GALATHEA NCT02138916 | N = 1743 | <ul style="list-style-type: none"> • ARM 1: 30 mg Q4w SC • ARM 2: 100 mg Q8w SC • ARM 3: Placebo SC 48-week study Global study – 21 countries | <ul style="list-style-type: none"> • Rate of COPD Exacerbation | <ul style="list-style-type: none"> • FSI Q3 14 • Est completion date Q4 17 |



Tralokinumab (anti-IL-13)

Asthma development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--|---------------|---|---|---|
| Adults with Uncontrolled Severe Asthma | Phase III STRATOS 1 NCT02161757 | N = 1140 | <ul style="list-style-type: none"> • <u>Cohort 1:</u> • ARM 1: Tralokinumab dose regimen 1 SC • ARM 2: Placebo SC • <u>Cohort 2:</u> • ARM 1: Tralokinumab dose regimen 2 SC • ARM 2: Placebo SC <p>• 2:1 randomisation in both cohorts</p> <p>Global study – 4 countries</p> | <p>Primary Endpoint</p> <ul style="list-style-type: none"> • Annual asthma exacerbation rate <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • 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) | <ul style="list-style-type: none"> • FSI Q3 14 • Primary completion Q2 17 |
| Adults with Uncontrolled Severe Asthma | Phase III NCT02194699 | N = 770 | <ul style="list-style-type: none"> • ARM 1: Tralokinumab SC • ARM 2: Placebo SC • 1:1 randomisation <p>Global study – 11 countries including Japan</p> | <p>Primary Endpoint</p> <ul style="list-style-type: none"> • Annual asthma exacerbation rate <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • 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) | <ul style="list-style-type: none"> • Planned FSI Q4 14 • Primary completion Q3 17 |



LABA/LAMA (PT003) & LAMA (PT001)

COPD development programme

| Patient Population | Phase Study | # of patients | Design G = Glycopyrronium, F = Formoterol fumarate | Endpoint(s) | Status |
|------------------------------|---|---------------|---|---|---|
| Moderate to Very Severe COPD | Phase III PINNACLE 1 NCT01854645 | N = 2054 | <ul style="list-style-type: none"> ARM 1: GFF MDI (PT003) 14.4/9.6 µg BiD ARM 2: GP MDI (PT001) 14.4 µg BiD ARM 3: FF MDI (PT005) 9.6 µg BiD ARM 4: Open-label tiotropium bromide inhalation powder QD ARM 5: Placebo MDI BiD <p>24 week study US, Australia, New Zealand</p> | <ul style="list-style-type: none"> Change from baseline in morning pre-dose trough FEV₁ | <ul style="list-style-type: none"> FSI Q2 13 LSI Q3 14 Est. completion date Q2 15 Est. external presentation 2016 |
| Moderate to Very Severe COPD | Phase III PINNACLE 2 NCT01854658 | N = 1614 | <ul style="list-style-type: none"> ARM 1: GFF MDI (PT003) 14.4/9.6 µg BiD ARM 2: GP MDI (PT001) 14.4 µg BiD ARM 3: FF MDI (PT005) 9.6 µg BiD ARM 4: Placebo MDI BiD <p>24 week study US, Australia, New Zealand</p> | <ul style="list-style-type: none"> Change from baseline in morning pre-dose trough FEV₁ | <ul style="list-style-type: none"> FSI Q3 13 LSI Q3 14 Est. completion date Q2 15 Est. external presentation 2016 |
| Moderate to Very Severe COPD | Phase III PINNACLE 3 NCT01970878 | N = 850 | <ul style="list-style-type: none"> ARM 1: GFF MDI (PT003) 14.4/9.6 µg BiD ARM 2: GP MDI (PT001) 14.4 µg BiD ARM 3: FF MDI (PT005) 9.6 µg BiD ARM 4: Open-label tiotropium bromide inhalation powder QD <p>28 week extension US, Australia, New Zealand</p> | <ul style="list-style-type: none"> Overall safety, tolerability and efficacy | <ul style="list-style-type: none"> FSI Q4 13 LSI Q3 14 Est. completion date Q2 15 Est. external presentation 2016 |



Anti-IL-17RA (brodalumab)

Psoriasis & psoriatic arthritis development programmes

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|---|---------------|--|---|--|
| Moderate to severe plaque psoriasis | Phase III AMAGINE-1 NCT01708590 | N = 661 | <ul style="list-style-type: none"> • ARM 1: 210 mg brodalumab SC • ARM 2: 140 mg brodalumab SC • ARM 3: placebo SC | <ul style="list-style-type: none"> • PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12 | <ul style="list-style-type: none"> • Primary data Q2 14 |
| Moderate to severe plaque psoriasis | Phase III AMAGINE-2 NCT01708603 | N = 1800 | <ul style="list-style-type: none"> • ARM 1: 210 mg brodalumab SC • ARM 2: 140 mg brodalumab SC • ARM 3: 45 or 90 mg ustekinumab SC • ARM 4: placebo SC | <ul style="list-style-type: none"> • PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12 | <ul style="list-style-type: none"> • FSI Q3 12 • Est completion date H2 14 |
| Moderate to severe plaque psoriasis | Phase III AMAGINE-3 NCT01708629 | N = 1881 | <ul style="list-style-type: none"> • ARM 1: 210 mg brodalumab SC • ARM 2: 140 mg brodalumab SC • ARM 3: 45 or 90 mg ustekinumab SC • ARM 4: placebo SC | <ul style="list-style-type: none"> • PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12 | <ul style="list-style-type: none"> • FSI Q3 12 • Est completion date H2 14 |
| Moderate to severe Psoriatic Arthritis | Phase II NCT01516957 | N = 156 | <ul style="list-style-type: none"> • ARM 1: 280 mg brodalumab SC • ARM 2: 210 mg brodalumab SC • ARM 3: 140 mg brodalumab SC • ARM 4: placebo SC | <ul style="list-style-type: none"> • ACR20 response at wk 12 | <ul style="list-style-type: none"> • Primary data Q4 12 • OLE ongoing, FSI Q1 14 • External presentation 12w data EULAR 2013, 24w data ACR 2013 |
| Adult subjects with Psoriatic Arthritis | Phase III AMVISION-1 NCT02029495 | N = 630 | <ul style="list-style-type: none"> • ARM 1: 210mg brodalumab SC • ARM 2: 140 mg brodalumab SC • ARM 3: placebo SC | Primary: <ul style="list-style-type: none"> • ACR20 response at wk 16 Secondary <ul style="list-style-type: none"> • Radiographic assessment of joints • PASI 75, HAQ-DI and PSI | <ul style="list-style-type: none"> • FSI March 2014 • Recruitment Ongoing • Est primary completion Q1 16 |
| Adult subjects with Psoriatic Arthritis | Phase III AMVISION-2 NCT02024646 | N = 495 | <ul style="list-style-type: none"> • ARM 1: 210mg brodalumab SC • ARM 2: 140 mg brodalumab SC • ARM 3: placebo SC | <ul style="list-style-type: none"> • ACR20 response at wk 16 | <ul style="list-style-type: none"> • FSI March 2014 • Recruitment Ongoing • Est primary completion Q1 16 |

Lesinurad (SURI)

Gout development programme

| Patient Population | Phase Study | # of patients | Design | Primary endpoint | Status |
|---|--|---------------|---|--|---|
| Gout with Inadequate Hypouricemic Response to Allopurinol | Phase III CLEAR 1 NCT01510158 | N = 600 | <ul style="list-style-type: none"> ARM 1: Placebo ARM 2: lesinurad 200 mg QD ARM 3: lesinurad 400 mg QD All arms: SOC allopurinol QD | <ul style="list-style-type: none"> Proportion of subjects with an sUA level that is < 6.0 mg/dL by Month 6 | <ul style="list-style-type: none"> FSI Q1 12 LSI Q3 13 Study complete, PR issued Est external presentation Q4 14 (ACR) |
| Gout with Inadequate Hypouricemic Response to Allopurinol | Phase III CLEAR 2 NCT01493531 | N = 600 | <ul style="list-style-type: none"> ARM 1: Placebo ARM 2: lesinurad 200 mg QD ARM 3: lesinurad 400 mg QD All arms: SOC allopurinol QD | <ul style="list-style-type: none"> Proportion of subjects with an sUA level that is < 6.0 mg/dL by Month 6 | <ul style="list-style-type: none"> FSI Q4 11 LSI Q2 13 Study complete, PR issued Est external presentation Q4 14 (ACR) |
| Tophaceous Gout | Phase III CRYSTAL NCT01510769 | N = 315 | <ul style="list-style-type: none"> ARM 1: Placebo ARM 2: lesinurad 200 mg QD ARM 3: lesinurad 400 mg QD All arms: febuxostat 80 mg QD | <ul style="list-style-type: none"> Proportion of subjects with an sUA level that is < 5.0 mg/dL by Month 6 | <ul style="list-style-type: none"> FSI Q1 12 LSI Q2 13 Study complete, PR issued Est ext. presentation Q2 15 (EULAR) |
| Gout with Intolerance or Contraindication to a Xanthine Oxidase Inhibitor | Phase III LIGHT NCT01508702 | N = 200 | <ul style="list-style-type: none"> Arm 1: Placebo Arm 2: lesinurad 400 mg QD | <ul style="list-style-type: none"> Proportion of subjects with an sUA level that is < 6.0 mg/dL at Month 6 | <ul style="list-style-type: none"> FSI Q1 12 LSI Q2 13 Study complete, press release issued Est ext. presentation Q2 15 (EULAR) |
| Gout previously enrolled LIGHT study | Phase III LIGHT Ext NCT01650246 | N = 143 | All arms: open-label lesinurad 400 mg QD | <ul style="list-style-type: none"> Assess the long-term efficacy and safety of lesinurad monotherapy. | <ul style="list-style-type: none"> FSI Q4 12 LSI Q1 14 Study complete Est ext. presentation Q2 15 (EULAR) |
| Gout previously enrolled in studies CLEAR 1 & 2 | Phase III CLEAR Ext NCT01808131 | N ≤ 200 | <ul style="list-style-type: none"> ARM 1: lesinurad 200 mg QD ARM 2: lesinurad 400 mg QD All arms: SOC allopurinol QD | <ul style="list-style-type: none"> Assess the long-term efficacy and safety of lesinurad in combination with allopurinol. | <ul style="list-style-type: none"> FSI Q1 13 LSI Q2 14 Study ongoing |
| Gout previously enrolled in CRYSTAL study | Phase III CRYSTAL Ext NCT01808144 | N ≤ 315 | <ul style="list-style-type: none"> ARM 1: lesinurad 200 mg QD ARM 2: lesinurad 400 mg QD All arms: febuxostat 80 mg QD | <ul style="list-style-type: none"> Assess the long-term efficacy and safety of lesinurad in combination with febuxostat. | <ul style="list-style-type: none"> FSI Q1 13 LSI Q2 14 Study ongoing |

CAZ-AVI (BLI/cephalosporin SBI)

Serious infections development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--|---------------|---|--|---|
| Hospitalised patients with complicated intra-abdominal infections | Phase III RECLAIM-1 NCT01499290 | N = 490 | <ul style="list-style-type: none"> • ARM 1: CAZ-AVI 2000/500mg plus Metronidazole IV • ARM 2: Meropenem IV <p>Global study – 20 countries</p> | <ul style="list-style-type: none"> • Co primary of: <ul style="list-style-type: none"> (i) clinical response at TOC (MITT) (ii) clinical response at TOC (i.e. clinically evaluable) | <ul style="list-style-type: none"> • FSI Q1 12 • LSI Q2 14 • Completion date Q3 14, PR issued • Est external presentation Q2 15 |
| Hospitalised patients with complicated intra-abdominal infections | Phase III RECLAIM-2 NCT01500239 | N = 576 | <ul style="list-style-type: none"> • ARM 1: CAZ-AVI 2000/500mg plus Metronidazole IV • ARM 2: Meropenem IV <p>Global study – 21 countries</p> | <ul style="list-style-type: none"> • Co primary of: <ul style="list-style-type: none"> (i) clinical response at TOC (MITT) (ii) clinical response at TOC (i.e. clinically evaluable) | <ul style="list-style-type: none"> • FSI Q2 12 • LSI Q2 14 • Completion date Q3 14, PR issued • Est external presentation Q2 15 |
| Hospitalised Adults With complicated urinary tract Infections | Phase III RECAPTURE-1 NCT01595438 | N = 520 | <ul style="list-style-type: none"> • ARM 1: CAZ-AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • ARM 2: Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim <p>Global study – 26 countries</p> | <ul style="list-style-type: none"> • Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT) | <ul style="list-style-type: none"> • FSI Q4 12 • LSI Q3 14 • Est completion date Q2 15 • Est external presentation Q3 15 |
| Hospitalised patients with complicated urinary tract infections | Phase III RECAPTURE-2 NCT01599806 | N = 511 | <ul style="list-style-type: none"> • ARM 1: CAZ-AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • ARM 2: Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim <p>Global study – 25 countries</p> | <ul style="list-style-type: none"> • Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT) | <ul style="list-style-type: none"> • FSI Q4 12 • LSI Q3 14 • Est completion date Q2 15 • Est external presentation Q3 15 |



CAZ-AVI (BLI/cephalosporin SBI)

Serious infections development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--|---------------|---|---|--|
| Patients with complicated urinary tract infections and complicated intra-abdominal infections | Phase III REPRISE NCT01644643 | N = 333 | <ul style="list-style-type: none"> • ARM 1: CAZ-AVI 2000/500mg plus Metronidazole IV • ARM 2: Best available therapy <p>Global study – 30 countries</p> | <ul style="list-style-type: none"> • Patients with clinical cure at the Test of Cure visit in the microbiological intent to treat analysis set | <ul style="list-style-type: none"> • FSI Q1 13 • LSI Q3 14 • Est completion date Q2 15 • Est external presentation 2015 |
| Hospitalised patients with complicated intra-abdominal infections | Phase III RECLAIM-3 NCT01726023 | N = 404 | <ul style="list-style-type: none"> • ARM 1: CAZ-AVI 2000/500mg plus Metronidazole IV • ARM 2: Meropenem IV <p>Asia-focused study – 3 countries (China, Vietnam & Korea)</p> | <ul style="list-style-type: none"> • Clinical Cure at the TOC visit in the MITT analysis set | <ul style="list-style-type: none"> • FSI Q1 13 • LSI Q4 14 • Est completion date Q1 15 • Est external presentation 2015 |
| Hospitalised patients with nosocomial pneumonia infections, including hospital acquired pneumonia (HAP) and ventilator associated pneumonia (VAP) | Phase III REPROVE NCT01808092 | N =1660 | <ul style="list-style-type: none"> • ARM 1: CAZ-AVI 2000/500mg IV • ARM 2: Meropenem IV <p>Global study – 24 countries</p> | <ul style="list-style-type: none"> • Proportion of patients with clinical cure at the TOC visit in the cMITT and CE analysis sets (co-primary analyses). | <ul style="list-style-type: none"> • FSI Q2 13 • LSI Q2 16 • Est completion date Q3 16 • Est external presentation beyond planning horizon |



BACE (AZD3293)

Alzheimer's Disease development programme

| Patient Population | Phase Study | # of Patients | Design | Endpoint(s) | Status |
|---|--|---------------|---|--|--|
| Healthy volunteers and Alzheimer's Disease Patients | Phase I MAD Study NCT01795339 | N = 56 | <ul style="list-style-type: none"> • Active ARMS: <ul style="list-style-type: none"> • (Part 1) AZD3293 MAD starting with 5 mg • (Part 2) Multiple doses (12 days) of AZD3293 one to up to 3 dosage levels • Comparator ARM: Placebo <p>1 site in US</p> | <ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs • PK • PD (Aβ40 and 42 plasma and CSF) | <ul style="list-style-type: none"> • Study completed. • Data from part 1 presented at CTAD Conference November 2013. • 2 more presentations of data in March and July 2014 • AD patient data (Part 2) to be presented at CTAD Conference November 2014 |
| Healthy Volunteers | Phase I JSMAD Study NCT02005211 | N = 40 | <ul style="list-style-type: none"> • Active ARMS: Ascending AZD3293 SAD (15, 50, 150 mg planned) and MAD (15, 50 mg doses planned) • Comparator ARM: placebo <p>1 site in Japan</p> | <ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs • PK • PD (Aβ 40 and 42 plasma) | <ul style="list-style-type: none"> • Study in reporting phase • FSI Q4 2013 • LSI Q3 2014 |
| Alzheimer's Disease Patients | Phase II/III Amaranth Study NCT02245737 | N=1551 | <ul style="list-style-type: none"> • ARM 1: AZD3293 20 mg once daily • ARM 2: AZD3293 50 mg once daily • ARM 3: placebo once daily • 24-month treatment duration <p>Approx. 150 sites in 15 countries</p> | <ul style="list-style-type: none"> • Change in Clinical Dementia Rating Sum of Boxes (CDR-SB) • Changes in Cognitive (ADAS-Cog 13) and functional (ADCS-ADL) scales • Changes in biomarkers and imaging assays • Safety and tolerability | <ul style="list-style-type: none"> • FSI Q3 2014 (planned) • Estimated external presentation beyond planning horizon |



AstraZeneca

Early development programmes

3Q 2014 Results Update

Tenapanor/AZD1722 (NHE3 inhibitor)

Phase II development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--------------------------|---------------|---|--|--|
| End Stage Renal Disease (ESRD) patients on hemodialysis (HD) with Hyperphosphatemia | Phase IIb NCT02081534 | N = 150 | <ul style="list-style-type: none"> • ARM 1: AZD1722, 1 mg BiD • ARM 2: AZD1722, 3 mg BiD • ARM 3: AZD1722, 10 mg BiD • ARM 4: AZD1722, 30 mg BiD • ARM 5: AZD1722, 3 mg OD • ARM 6: AZD1722, 30 mg OD • ARM 7: Placebo <p>Conducted in the US, UK, Slovakia, Poland</p> | <ul style="list-style-type: none"> • Change in serum phosphate levels • Dose response relationship of AZD1722 on serum phosphate levels • Number of patients reaching serum phosphate goal levels vs placebo | <ul style="list-style-type: none"> • FSI Q1 14 • LSI Q3 14 • Completion date Q1 15 • Est external presentation Q4 15 |
| Patients with ESRD on HD | Phase IIa NCT01764854 | N = 86 | <ul style="list-style-type: none"> • ARM 1: AZD1722, starting dose 45 mg BiD, down titration based on tolerability • ARM 2: Placebo <p>Conducted in the US</p> | <ul style="list-style-type: none"> • Reduction in mean weekly interdialytic weight gain (IDWG) • Effect of AZD1722 on IDWG after weekly intervals of treatment | <ul style="list-style-type: none"> • FSI Q1 13 • LSI Q4 13 • Completion date Q1 14 • Est external presentation Q1 16 |
| Patients with Chronic Kidney Disease (CKD), Type 2 Diabetes and Albuminuria | Phase IIa NCT01847092 | N = 140 | <ul style="list-style-type: none"> • ARM 1: AZD1722, starting dose 15 mg BiD, dose escalation based on tolerability (max 60 mg BiD) • ARM 2: Placebo <p>Conducted in the US, Germany</p> | <ul style="list-style-type: none"> • Changes in Urine Albumin to Creatinine Ratio (UACR) • Effects on UACR, eGFR, blood pressure, p-NT-proBNP, s-cardiac troponin, u-aldosterone, p-renin activity, and bioimpedence. | <ul style="list-style-type: none"> • FSI Q2 13 • LSI Q4 14 • Completion date Q2 15 • Est external presentation Q4 15 |
| Patients with constipation predominant Irritable Bowel Syndrome (IBS-C) | Phase IIb NCT01923428 | N = 360 | <ul style="list-style-type: none"> • ARM 1: AZD1722, 5 mg BiD • ARM 2: AZD1722, 20 mg BiD • ARM 3: AZD1722, 50 mg BiD • ARM 4: Placebo <p>Conducted in the US</p> | <ul style="list-style-type: none"> • Percent Complete Spontaneous Bowel Movement (CSBM) responders • Percent abdominal pain responders • Percent overall responder for both • CSBM and abdominal pain | <ul style="list-style-type: none"> • FSI Q3 13 • LSI Q2 14 • Completed, PR issued by Ardelyx • Est external presentation Q2 15 |



Hormone Modulator (AZD4901)

Phase II clinical development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--------------------------|---------------|--|---|---|
| Polycystic Ovary Syndrome patients with amenorrhea or oligomenorrhea | Phase IIa NCT01872078 | N = 56 | <ul style="list-style-type: none">• ARM 1: AZD4901 20 mg QD• ARM 2: AZD4901 20 mg BiD• ARM 3: AZD4901 40 mg BiD• ARM 4: placebo <p>28 day dosing period</p> <p>Study sites in US, UK, Germany</p> | <ul style="list-style-type: none">• Change from baseline at day 7 in Luteinizing Hormone AUC(0-8) <p>Secondary endpoints:</p> <ul style="list-style-type: none">• Change from baseline in free and total testosterone at day 7 & day 28 | <ul style="list-style-type: none">• FSI Q2 13• LSI Q2 14• Est completion Q4 14• External presentation ENDO Q1 15 and ESHRE Q2 15 |



MCH (AZD1979)

Phase I clinical development programme

| Patient Population | Phase Study | # of Patients | Design | Primary Endpoint | Status |
|--------------------|-------------------------------|--------------------------------|---|---|---|
| Healthy subjects | Phase I NCT02072993 | N = 56 planned (72 maximum) | <ul style="list-style-type: none">• Single Ascending Dose study – single-center, single-blind, randomized and placebo-controlled.• 7 planned cohorts/dose levels | <ul style="list-style-type: none">• Safety and tolerability | <ul style="list-style-type: none">• FSI Q2 2014.• Study stopping criteria met at dose level 4 (dosing June 17-18). |



WEE-1 (AZD1775)

Solid tumours development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|-------------------------|---------------|--|--|--|
| p53 mutant PSR ovarian cancer | Phase II NCT01357161 | N = 120 | <ul style="list-style-type: none"> ARM 1: carbo/paclitaxel + AZD1775 225mg ARM 2: carbo/paclitaxel + placebo <p>Global study 9 countries</p> | <ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint. | <ul style="list-style-type: none"> FSI Q4 11 LSI Q3 14 Est completion Q1 15 Est external presentation Q2 16 (ASCO) |
| Previously Untreated Stage IV Non-Squamous NSCLC with TP53 mutations | Phase II NCT02087241 | N = 130 | <ul style="list-style-type: none"> ARM 1: carboplatin + pemetrexed + AZD1775 225 mg BiD ARM 2: carboplatin + pemetrexed + placebo <p>6 patients safety lead in Conducted in US</p> | <ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint. | <ul style="list-style-type: none"> FSI Q1 14 LSI Q2 15 Est completion Q2 16 Est external presentation Q2 17 (ASCO) |
| Previously Treated NSCLC with TP53 mutations | Phase II NCT02087176 | N = 135 | <ul style="list-style-type: none"> ARM 1: docetaxel + AZD1775 225 mg BiD ARM 2: docetaxel+ placebo <p>20-25 patient run in for safety and efficacy Conducted in US</p> | <ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint. | <ul style="list-style-type: none"> FSI Q1 14 LSI Q2 15 Est completion Q2 16 Est external presentation Q2 17 (ASCO) |



FGFR (AZD4547)

Solid tumours development programme

| Patient population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--|----------------------------|--|--|---|
| Advanced cancer who have failed standard therapy or for whom no standard therapy exists | Phase I NCT01213160 | N = 33 | <ul style="list-style-type: none"> • 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. 8 patients) <p>Conducted in Japan</p> | <ul style="list-style-type: none"> • Part A: MTD and Recommended dose for Parts B and C • Part B: Safety and tolerability and preliminary anti-tumour activity | <p>Completed Q2 13</p> <ul style="list-style-type: none"> • Est external presentation beyond planning horizon |
| Female ER+ Breast cancer patients whose disease has progressed following treatment with one prior endocrine therapy | Phase II GLOW NCT01202591 | N = 900 | <ul style="list-style-type: none"> • Part A: AZD4547 in ascending multiple doses in combination with 25mg exemestane • Part B: <ul style="list-style-type: none"> • ARM 1: AZD4547 (dose from part A) + fulvestrant • ARM 2: placebo + fulvestrant <p>Patients with FGFR1 polysomy (30 patients) or FGFR1 amplification (60 patients)</p> | <ul style="list-style-type: none"> • 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 | <p>Recruitment closed Q2 14</p> <ul style="list-style-type: none"> • Est external presentation beyond planning horizon |
| Advanced gastro-oesophageal cancer | Phase II SHINE NCT01457846 | N = 71 | <ul style="list-style-type: none"> • 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) | <ul style="list-style-type: none"> • Progression Free Survival • Key Secondary: Overall survival/Tumour size | <p>Recruitment closed after an interim analysis Q2 13</p> <ul style="list-style-type: none"> • Est external presentation Q4 14 |
| <p>Stage IIIB-IV NSCLC patients</p> <p>Biomarker-Targeted Second-Line Therapy</p> | Phase II/III Lung Master Protocol Partnered with NCI and SWOG NCT02154490 | N = 318 (AZD4547 arm only) | <p>5-Arm study based on biomarker expression</p> <ul style="list-style-type: none"> • ARM 1: MEDI4736Unmatched biomarker IVQ2W • ARM 2: AZD4547 (FGFR inhibitor) • ARM 3: CDK4/6 inhibitor • ARM 4: PI3K Inhibitor • ARM 5: HGFR Inhibitor | <ul style="list-style-type: none"> • Progression Free Survival (PFS) • Overall Survival (OS) | <ul style="list-style-type: none"> • AZD4547 FSI Q4 14) • Est completion date Q2 22 (final data collection for primary outcome measure Ph III) • Est external presentation beyond planning horizon |

FGFR (AZD4547) continued

Solid tumours development programme

| Patient population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|------------------------|---------------|---|---|---|
| Advanced cancer who have failed standard therapy or for whom no standard therapy exists | Phase I NCT00979134 | N = 94 | <ul style="list-style-type: none">• 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 | <ul style="list-style-type: none">• Part A: MTD and Recommended dose for Parts B and C• Part B and C: Safety and tolerability, PK and preliminary anti-tumour activity | Completed Q1 14 <ul style="list-style-type: none">• Est external presentation beyond planning horizon |



Volitinib (AZD6094) (HMPL-504) (cMET)

Phase I/II development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--------------------------------------|-------------------------|---------------|--|---|---|
| Advanced Cancer (All comers) | Phase I NCT01773018 | N = 50 | <ul style="list-style-type: none"> • Dose escalation study Conducted in Australia | <ul style="list-style-type: none"> • Safety and tolerability | <ul style="list-style-type: none"> • FSI Q1 12 • LSI Q3 15 • Est completion Q4 15 • Est external presentation Q2 15 (AACR & ASCO) |
| Advanced Cancer (All comers) | Phase I NCT01985555 | N =70 | <ul style="list-style-type: none"> • Dose escalation study Conducted in China | <ul style="list-style-type: none"> • Safety and tolerability | <ul style="list-style-type: none"> • FSI Q2 13 • LSI Q2 15 • Est completion Q3 15 • Est external presentation Q2 15 (ASCO) |
| Advanced Gastric Cancer (All comers) | Phase I NCT02252913 | N =50 | <ul style="list-style-type: none"> • Dose escalation study Conducted in China | <ul style="list-style-type: none"> • Safety and tolerability | <ul style="list-style-type: none"> • FSI Q4 14 • LSI Q2 16 • Est completion Q4 16 |
| Papillary Renal Cell Cancer | Phase II NCT02127710 | N =75 | <ul style="list-style-type: none"> • Single arm study: AZD6094 600mg QD Conducted in UK, US, Canada | <ul style="list-style-type: none"> • Overall Response Rate | <ul style="list-style-type: none"> • FSI Q2 14 • LSI Q2 15 • Est completion Q4 15 • Est external presentation Q2 16 (ASCO) |



TORC 1/2 (AZD2014)

Solid tumours development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|---|---------------|--|---|---|
| 2nd line ER+ Metastatic Breast Cancer | Phase II MANTA Partnered* NCT02216786 | N = 300 | <ul style="list-style-type: none"> • ARM 1: Fulvestrant • ARM 2: Fulvestrant + AZD2014 50mg BD continuous dosing • ARM 3: Fulvestrant + AZD2014 125mg BD two days on, 5 off • ARM 4: Fulvestrant + everolimus <p>The study will be conducted in Europe</p> | <ul style="list-style-type: none"> • Progression Free Survival • Overall Survival is a secondary endpoint | <ul style="list-style-type: none"> • FSI Q2 14 • LSI Q4 15 • Est completion Q2 17 • Est external presentation Q4 17 |
| Advanced Solid Malignancies | Phase I NCT01026402 | N = 135 | <ul style="list-style-type: none"> • SAD and MAD with dose expansion. Continuous and intermittent dosing. <p>Sites in UK</p> | <ul style="list-style-type: none"> • Safety and tolerability of AZD2014 | <ul style="list-style-type: none"> • FSI Q4 09 • LSI Q2 14 • Est completion Q3 14 • External presentation Q2 12 (ASCO) |
| ER+ Advanced Metastatic Breast Cancer | Phase I NCT01597388 | N = 92 | <ul style="list-style-type: none"> • SAD and MAD. Continuous and intermittent dosing schedules in combination with fulvestrant <p>Sites in US</p> | <ul style="list-style-type: none"> • Safety and tolerability of AZD2014 in combination with fulvestrant • Determination of steady state PK profile of AZD2014 in combination with fulvestrant | <ul style="list-style-type: none"> • FSI Q2 12 • LSI Q1 15 • Est completion Q3 15 • Est external presentation Q4 14 (SABCS) |

*Collaborative study. Peter Schmid PI. Sponsor QMUL



AKT (AZD5363)

Solid tumours development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--------------------------|----------------|--|---|--|
| Breast and Gynaecological cancers with PIK pathway mutation | Phase I NCT01226316 | N = 20 per arm | <p>Monotherapy AZD5363 480mg BD 4 days on 3 days off</p> <ul style="list-style-type: none"> • 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 <p>Possible expansion up to 120 patients per arm</p> | <ul style="list-style-type: none"> • Safety and tolerability • Response Rate (ORR) | <ul style="list-style-type: none"> • FSI Q3 13 • Est completion Q3 15 |
| ER+ breast cancer receiving 1 st treatment with paclitaxel in the advanced setting | Phase IIb NCT01625286 | N =100 | <ul style="list-style-type: none"> • ARM 1: AZD5363 + paclitaxel • ARM 2: Paclitaxel alone <p>Two strata: PIK3CA mutation positive vs Mutation not detected</p> | <ul style="list-style-type: none"> • Progression Free survival (PFS) • Response rate (ORR) & overall survival are secondary endpoints | <ul style="list-style-type: none"> • Est completion Q4 16 • Est external presentation of Part A dose escalation in Q2 15 |
| All-comers solid tumours | Phase I NCT01895946 | N = min 12-24 | <ul style="list-style-type: none"> • Comparison of PK between new tablet and original capsule formulation and preliminary assessment of food effect on tablet PK • AZD5363 monotherapy 480mg bd 4 days on 3 days off • 12 pts for each of formulation switch and food effect | <ul style="list-style-type: none"> • PK | <ul style="list-style-type: none"> • Tablet-capsule comparison completed in Q3 14 & formulations declared comparable. • Assessment of food effect ongoing with completion est. Q2 15 |



PI3Kb/d (AZD8186)

Solid tumours development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|------------------------|---------------|---|--|---|
| Advanced CRPC/SqNSCLC /TNBC and patients with known PTEN-deficient tumours | Phase I NCT01884285 | N = 96 | <ul style="list-style-type: none">• Part A: AZD8186 monotherapy in ascending intermittent doses in 2 schedules• Part B: AZD8186 monotherapy at recommended dose and schedule(s) from Part A in PTEN deficient patients with advanced cancer Study conducted in Canada, US & UK | <ul style="list-style-type: none">• Part A: PK, MTD and Recommended dose and schedule(s) for Part B• Part B: Safety and tolerability and preliminary assessment of antitumor activity (POM) | <ul style="list-style-type: none">• FSI Q3 13• Est completion Q4 16• Est external presentation Q2 15 (AACR or ASCO) |



ISIS-AR (AZD5312)

Solid tumours development programme

| Patient population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|------------------------|---------------|--|---|--|
| Advanced solid tumours with androgen receptor pathway as a potential factor | Phase I NCT02144051 | N = 90 | <p>Part A: Dose escalation</p> <ul style="list-style-type: none"> AZD5312 in ascending multiple doses given iv (c. 30 patients) <p>Part B: Dose expansion</p> <ul style="list-style-type: none"> AZD5312 at recommended dose from Part A, given iv <ul style="list-style-type: none"> Arm 1: Prostate cancer patients who have received a second generation antihormonal therapy (eg. abiraterone, enzalutamide) but have not responded (n=20). AZD5312 at RP2D Arm 2: Prostate cancer patients who have initially responded to a second generation anti-hormonal therapy, but later relapsed (n=20). Arm 3: Non-mCRPC patient population (eg. breast, bladder, ovarian) expansion, where AR pathway may be a potential factor (n=20). | <ul style="list-style-type: none"> Part A: MTD and Recommended dose for Parts B. Safety and tolerability and preliminary anti-tumour activity Part B (prostate patients) Response rate, blood PSA, circulating tumour cell enumeration, disease progression | <ul style="list-style-type: none"> FSI Q2 14 Est completion Q2 16 Est external presentation beyond planning horizon |



STAT3 (AZD9150)

Haematological malignancies development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--------------------|--|---------------|---|--|--|
| HCC | Phase I NCT01839604 | N =64 | <ul style="list-style-type: none">• Dose-escalation and dose-expansion study• IV Study conducted in Japan, Korea, Taiwan and Hong Kong | <ul style="list-style-type: none">• Safety and tolerability .• Recommended phase II dose and schedule | <ul style="list-style-type: none">• FSI Q2 13• Est completion Q2 15• Est external presentation Q4 14 |
| DLBCL | Phase I/II* Partnered ISIS NCT01563302 | N = 55 | <ul style="list-style-type: none">• Dose-escalation and dose-expansion study• IV Study conducted in US | <ul style="list-style-type: none">• Safety and tolerability .• Recommended phase II dose and schedule | <ul style="list-style-type: none">• FSI Q1 12• Est completion Q2 15• Est external presentation Q2 15 |



ATR (AZD6738)

Solid tumours development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--------------------|------------------------|---------------|---|---|---|
| Solid tumours | Phase I NCT02264678 | N = 119 | • MAD North America – 1 site Europe – 3 sites | • Safety and tolerability • Efficacy | • FSI Q4 2014 • Est completion Q4 2016 • Estimated external presentation 2017 |



LABA/LAMA/ICS (PT010)

COPD & Asthma development programme

| Patient Population | Phase Study | # of patients | Design (B/BD)= Budesonide, FF = Formoterol fumarate) | Endpoint(s) | Status |
|--|-------------------------|---------------|---|---|---|
| Moderate to Severe COPD | Phase II NCT02196077 | N = 160 | <ul style="list-style-type: none"> • ARM 1: BFF MDI 320/9.6 µg BiD • ARM 2: BFF MDI 160/9.6 µg BiD • ARM 3: BFF MDI 80/9.6 µg BiD • ARM 4: BD MDI 320 µg BiD • ARM 5: FF MDI 9.6 µg BiD <p>28 day study, US</p> | <ul style="list-style-type: none"> • Forced expiratory volume in 1 second area under the curve from 0 to 12 hours (FEV₁ AUC₀₋₁₂) | <ul style="list-style-type: none"> • FSI Q3 14 • LSI Q3 14 • Est. completion date Q2 15 • Est. external presentation 2016 |
| Adult Mild to Moderate Persistent Asthma | Phase II NCT02105012 | N = 150 | <ul style="list-style-type: none"> • ARM 1: BD MDI 320 µg BiD • ARM 2: BD MDI 160 µg BiD • ARM 3: BD MDI 80 µg BiD • ARM 4: BD MDI 40 µg BiD • ARM 5: Placebo MDI BiD <p>4 week study, US</p> | <ul style="list-style-type: none"> • Change from baseline in morning pre-dose trough forced expiratory volume in one second (FEV₁) | <ul style="list-style-type: none"> • FSI Q2 14 • LSI Q4 14 • Est. completion date Q3 15 • Est. external presentation 2016 |
| Healthy volunteers | Phase I NCT02189304 | N = 60 | <ul style="list-style-type: none"> • ARM 1: BGF MDI 320/14.4/9.6 µg • ARM 2: BFF MDI 160/14.4/9.6 µg • ARM 3: Symbicort Turbuhaler® 400/12 µg | <ul style="list-style-type: none"> • Overall safety • PK parameters AUC₀₋₁₂ and C_{max} | <ul style="list-style-type: none"> • FSI Q3 14 • LSI Q3 14 • Est. completion date Q4 14 • Est. external presentation 2015 |
| Japanese Healthy Volunteers | Phase I NCT02197975 | N = 28 | <ul style="list-style-type: none"> • ARM 1: BGF MDI 320/14.4/9.6 µg • ARM 2: BGF MDI 160/14.4/9.6 µg • ARM 3: Placebo MDI | <ul style="list-style-type: none"> • Overall safety • PK parameters AUC₀₋₁₂ and C_{max} | <ul style="list-style-type: none"> • FSI Q3 14 • LSI Q3 14 • Est. completion date Q4 14 • Est. external presentation 2015 |
| Japanese Healthy Volunteers | Phase I NCT02196714 | N = 24 | <ul style="list-style-type: none"> • ARM 1: GFF MDI 14.4/9.6 µg • ARM 2: GFF MDI 28.8/9.6 µg • ARM 2: GP MDI 14.4 µg • ARM 2: GP MDI 28.8 µg | <ul style="list-style-type: none"> • Overall safety • PK parameters AUC₀₋₁₂ and C_{max} | <ul style="list-style-type: none"> • FSI Q3 14 • LSI Q3 14 • Est. completion date Q4 14 • Est. external presentation 2015 |



MABA (AZD2115)

COPD clinical development programme

| Patient Population | Phase Study | # of Patients | Design | Endpoint(s) | Status |
|--------------------|--|---------------|--|--|--|
| Healthy subjects | Phase I NCT01283984 | N = 72 | <ul style="list-style-type: none"> • ARM 1: SAD AZD2115 as nebulised solution • ARM 2: Placebo | <ul style="list-style-type: none"> • Safety and tolerability following inhaled administration with single ascending dose | <ul style="list-style-type: none"> • FSI Q1 11 • Completed • Est. external presentation Q1 15 |
| Healthy subjects | Phase I NCT01445782 | N = 36 | <ul style="list-style-type: none"> • ARM 1: SAD and MAD AZD2115 as nebulised solution • ARM 2: Placebo <p>Conducted in UK.</p> | <ul style="list-style-type: none"> • Safety and tolerability following administration of multiple ascending inhaled doses | <ul style="list-style-type: none"> • FSI Q4 11 • Completed • Est. external presentation Q1 15 |
| COPD | Phase IIa MISTRAL NCT01498081 | N = 39 | <ul style="list-style-type: none"> • ARM 1: AZD2115, 25 µg (iNeb) • ARM 2: AZD2115, 80 µg (iNeb) • ARM 3: AZD2115, 240 µg (iNeb) • ARM 4: indacaterol, 150 µg • ARM 5: indacaterol, 150 µg + tiotropium, 18 µg • ARM 6: placebo <p>Conducted in Sweden and Poland.</p> | <ul style="list-style-type: none"> • Peak and trough FEV1 | <ul style="list-style-type: none"> • FSI Q1 12 • Completed • Est. external presentation 2016 |
| COPD | Phase IIa NCT02109406 | N = 30 | <ul style="list-style-type: none"> • ARM 1: AZD2115, 50 µg BID (pMDI) • ARM 2: AZD2115, 100 µg BID (pMDI) • ARM 3: placebo <p>Multiple dose, 3-way cross over</p> <p>Conducted in US.</p> | <ul style="list-style-type: none"> • FEV1 AUC(0-12) relative to baseline following chronic dosing on Day 15 | <ul style="list-style-type: none"> • FSI Q2 14 • Completed • Est. external presentation 2016 |



p38 inhibitor (AZD7624)

COPD development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---------------------------|--------------------------------|---------------|--|---|--|
| Healthy subjects | Phase I NCT01754844 | N = 40 | SAD <ul style="list-style-type: none"> Five different dose levels investigated vs placebo Inhaled (nebulised) administration <p>Study conducted in the UK</p> | <ul style="list-style-type: none"> Safety and tolerability following inhaled administration with single ascending dose | <ul style="list-style-type: none"> FSI: Q1 2013 Completed Estimated publication: 2015 |
| Healthy subjects and COPD | Phase I NCT01817855 | N = 44 | MAD <ul style="list-style-type: none"> Different dose levels investigated vs placebo in healthy volunteers and patients with COPD Inhaled (nebulised) administration <p>Study conducted in the UK</p> | <ul style="list-style-type: none"> Safety and tolerability in healthy subjects and patients with COPD following administration of multiple ascending inhaled doses | <ul style="list-style-type: none"> FSI: Q3 13 LSI: Q4 14 Estimated completion: Q4 14 Estimated publication: 2015 |
| Healthy subjects | Phase Ib LPS NCT01937338 | N = 60 | <ul style="list-style-type: none"> 2-way cross-over RCT Single administration of 1200µg of AZD7624 or placebo at 0.5 hours prior to lipopolysaccharide (LPS) challenge. Inhaled (nebulised) administration <p>Study conducted in the UK</p> | <ul style="list-style-type: none"> Effect on neutrophils in induced sputum after oral inhalation of LPS, compared to placebo | <ul style="list-style-type: none"> FSI: Q4 13 Completed Estimated publication: 2015 |
| COPD | Phase IIa NCT02238483 | N = 212 | <ul style="list-style-type: none"> ARM 1: AZD7624, 1.0mg ARM 2: placebo Inhaled (nebulised) administration <p>Study conducted in US, EU, South Africa & South America</p> | <ul style="list-style-type: none"> Effect on rate of exacerbations and lung function compared to placebo | <ul style="list-style-type: none"> FSI: Q4 14 LSI: Q4 15 Estimated publication: 2016 |

URAT1 (RDEA3170)

Gout development programme

| Patient Population | Phase Study | # of patients | Design | Primary endpoint | Status |
|--|-------------------------|---------------|---|--|---|
| Monotherapy study in Subjects with Gout | Phase II NCT01927198 | N = 160 | <ul style="list-style-type: none"> • Arm A: Placebo • Arm B: RDEA3170 5 mg QD • Arm C: RDEA3170 10 mg QD • Arm D: RDEA3170 12.5 mg QD | • Efficacy and Safety at Week 12 | <ul style="list-style-type: none"> • FSI Q3 13 • LSI Q4 13 • Study complete • Estimated external presentation Q2 15 |
| Monotherapy study in Japanese Patients with Gout or Asymptomatic Hyperuricemia | Phase II NCT02078219 | N = 200 | <ul style="list-style-type: none"> • Arm A: Placebo • Arm B: RDEA3170 5 mg QD, followed by 7.5 mg QD • Arm C: RDEA3170 10 mg QD, followed by 12.5 mg QD • Arm D: RDEA3170 12.5 mg QD, followed by 15 mg QD • Arm E: Open-label Allopurinol 100mg BID | • To compare the efficacy of RDEA3170 monotherapy at Week 16 with placebo and Allopurinol. | <ul style="list-style-type: none"> • FSI: Q1 14 • LSI: Q3 14 • Estimated completion: Q2 15 |
| Combination therapy study with febuxostat in Subjects with Gout | Phase II NCT02246673 | N = 200 | <ul style="list-style-type: none"> • Arm A: RDEA3170 2.5 mg QD • Arm B: RDEA3170 5.0 mg QD • Arm C: RDEA3170 10 mg QD • Arm D: RDEA3170 15 mg QD <p>*All arms include combination with 40 mg QD febuxostat for 7 days followed by combination with 80 mg QD febuxostat for 7 days</p> | • To assess the PK and PD profiles of RDEA3170 administered with febuxostat | <ul style="list-style-type: none"> • FSI planned Q4 14 • LSI estimated Q1 15 • Estimated completion: Q2 15 |



Infection early development

Serious infections development programme

| | Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--------------------------------------|---|--|------------------------------------|--|--|---|
| ATM-AVI (Aztreonam-Avibactam) | Healthy volunteers | Phase I NCT01689207 | N = 12 N = 56 N = 35 | <ul style="list-style-type: none"> Randomised, double-blind, 3-part study in healthy young and elderly volunteers given Aztreonam and Avibactam alone and in combination Part A: single 1 hour IV infusions Part B: single IV infusion on Days 1 and 11 and multiple (every 6 hr) IV infusions on Days 2-10. Various dose regimens of Aztreonam-Avibactam are being tested. Part C: multiple (every 6 hr) IV infusions Days 1-10 in healthy young and elderly volunteers <p>Single centre in UK</p> | <ul style="list-style-type: none"> Safety/tolerability Pharmacokinetics (secondary) | <ul style="list-style-type: none"> FSI Q4 12 LSI Q1 15 Est completion date Q2 15 Est presentation Q3 15 (ICAAC) |
| GyrAR (AZD0914) | Patients with uncomplicated gonorrhoea | Phase II Partnered NCT02257918 | N = 180 | <ul style="list-style-type: none"> Arm 1: AZD0914 single oral dose 2000mg Arm 2: AZD0914 single oral dose 3000mg Arm 3: Ceftriaxone single IM dose 500mg Multi center, US | <p>Primary:</p> <ul style="list-style-type: none"> Microbiological cure <p>Secondary:</p> <ul style="list-style-type: none"> Safety and tolerability | <ul style="list-style-type: none"> Planned FSI: Q4 2014 Est. completion: Q2 2015 Est. presentation: 2016 |
| Rib50s (AZD5847) | Extended Early Bactericidal Effect (EBA)* | Phase IIa NCT01516203 | N = 75 | <ul style="list-style-type: none"> ARM 1: AZD5847 500mg QD ARM 2: AZD5847 500mg BiD ARM 3: AZD5847 1200mg QD ARM 4: AZD5847 800mg BiD ARM 5: Placebo (Rifafour, weight based) <p>Study conducted in Cape Town, South Africa</p> | <ul style="list-style-type: none"> Rate of change in sputum colony forming unit (CFU) counts during 14 days of study drug administration (EBA 0-14) | <ul style="list-style-type: none"> LSI Q4 13 Completed |

* Study sponsored by the National Institutes for Allergy and Infectious Disease (NIAID)

MPO (AZD3241)

Parkinson's Disease development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|------------------------------|-------------------------|---------------|--|---|---|
| Healthy Subjects | Phase I NCT00729443 | N = 46 | <ul style="list-style-type: none"> • Active ARMS: SAD • Comparator ARM: placebo <p>1 site in Sweden</p> | <ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs • PK | <ul style="list-style-type: none"> • Study completed |
| Healthy Subjects | Phase I NCT01457807 | N = 18 | <ul style="list-style-type: none"> • Active ARMS: MAD • Comparator ARM: placebo <p>1 site in UK</p> | <ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs • PK | <ul style="list-style-type: none"> • Study completed |
| Healthy Subjects | Phase I NCT00914303 | N = 59 | <ul style="list-style-type: none"> • Active ARMS: MAD • Comparator ARM: placebo <p>1 site in Sweden</p> | <ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs • PK | <ul style="list-style-type: none"> • Study completed |
| Parkinson's Disease Patients | Phase II NCT01527695 | N = 24 | <ul style="list-style-type: none"> • ARM 1: AZD3241 600 mg BID for 8 weeks • ARM 2: Placebo <p>Randomization 3:1 active to placebo.</p> <p>3 sites in Sweden and Finland</p> | <ul style="list-style-type: none"> • Microglia activation represented by [11C]PBR28 binding <p>Secondary endpoints:</p> <ul style="list-style-type: none"> • PD symptoms measured by UPDRS • Plasma MPO activity | <ul style="list-style-type: none"> • Study completed • Poster presented at Movement Disorders Society meeting June 2014 |
| Parkinson's Disease Patients | Phase II NCT01603069 | N = 51 | <ul style="list-style-type: none"> • ARM 1: AZD3241 300 mg BID for 12 weeks • ARM 2: AZD3241 600 mg BID for 12 weeks • ARM 3: Placebo <p>Randomization 1:1:1 across arms</p> <p>13 sites in US</p> | <ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs <p>Secondary endpoints:</p> <ul style="list-style-type: none"> • PD symptoms measured by UPDRS • Plasma MPO activity | <ul style="list-style-type: none"> • Study completed • Poster presented at Movement Disorders Society meeting June 2014 |

Histamine H3 receptor inverse agonist (AZD5213)

Phase II clinical development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|-----------------------------|--------------------------|---------------|--|---|--|
| Tourette's Disorder | Phase IIa NCT01904773 | N = 18 | <ul style="list-style-type: none"> • Part 1: Single blind to determine tolerability and PK in adolescent age group (age ≥ 12 to < 18). • Part 2: Randomized, double-blind, six-period, three-treatment, cross-over <ul style="list-style-type: none"> • ARM 1: AZD5213 low dose • ARM 2: AZD5213 high dose • ARM 3: Placebo <p>US only study, 9 sites</p> | <ul style="list-style-type: none"> • Improvement in Total Tic Severity Score (TTS) on the Yale Global Tic Severity Scale (YGTSS) at the last day of receiving treatment. | <ul style="list-style-type: none"> • FSI Q4 13 • LSI Q3 14 • Est completion Q2 15 • Est external presentation 2015 |
| Painful Diabetic Neuropathy | Phase IIa NCT01928381 | N = 32 | <ul style="list-style-type: none"> • Part 1: Training to improve reliability to assess pain. • Part 2: Randomized, double-blind, three-period, three-treatment, cross-over <ul style="list-style-type: none"> • ARM 1: AZD5213 + Pregabalin • ARM 2: Pregabalin • ARM 3: Placebo <p>US only study, 9 sites</p> | <ul style="list-style-type: none"> • Significant change on average severity of pain (BPI-DPN). | <ul style="list-style-type: none"> • FSI Q4 13 • LSI Q4 14 • Est completion Q2 15 • Est external presentation 2015 |



NMDA (AZD6423)

Phase I clinical development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--------------------|------------------------|---------------|---|---|---|
| Healthy Volunteers | Phase I NCT01926366 | N = 64 | <ul style="list-style-type: none">• SAD/MAD: Ascending dose cohorts of n=8 (6 active drug, 2 placebo); IV administration• 8 dose cohorts planned (5 SAD, 3 MAD) | <ul style="list-style-type: none">• Safety and tolerability Additional endpoints: <ul style="list-style-type: none">• Pharmacokinetics• Pharmacodynamic biomarker (qEEG) | <ul style="list-style-type: none">• FSI Q3 13• LSI Q1 14• Study completed• Est. external presentation 2015 |



MedImmune

Early development programmes

3Q 2014 Results Update



Cardiovascular biologics early development

Phase I clinical development programme

| Compound | Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|-------------------------|--|------------------------|---------------|--|---|--|
| rhLCAT (MEDI6012) | Adults with stable Coronary Artery Disease and low HDL | Phase I NCT01554800 | N = 16 | • SAD IV | <ul style="list-style-type: none">• Safety• Changes in total HDL• Change in Cholesteryl Ester | • Completed by Alphacore |
| rh-Factor II (MEDI8111) | Healthy male subjects | Phase I NCT01958645 | N = 62 | • SAD IV administration UK study site | • Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, immunogenicity and physical examination | <ul style="list-style-type: none">• FSI Q4 13• LSI Q1 15• Est completion date Q1 15• Est external communication beyond planning horizon |



Anti-CD19 (MEDI-551)

Haematological malignancies development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|---------------------------|---------------|---|---|--|
| Adults with relapsed or refractory B-cell chronic lymphocytic leukemia (CLL) | Phase II NCT01466153 | N = 180 | <ul style="list-style-type: none"> • ARM 1: MEDI-551 IV (dose-level 1) and Bendamustine • ARM 2: MEDI-551 IV (dose-level 2) and Bendamustine • ARM 3: Rituxan and Bendamustine <p>Open label study</p> | <ul style="list-style-type: none"> • ORR, including Complete Response (CR) or Partial Response (PR) | <ul style="list-style-type: none"> • FSI Q1 12 • Est completion date Q1 16 • Est external presentation Q2 15 |
| Adults with relapsed or refractory B-cell diffuse large B-cell lymphoma (DLBCL) | Phase II NCT01453205 | N = 170 | <ul style="list-style-type: none"> • ARM 1: MEDI-551 dose level 1 and ICE/DHAP • ARM 2: MEDI-551 dose level 2 and ICE/DHAP • ARM 2: Rituxan + ICE/DHAP <p>Open label study</p> | <ul style="list-style-type: none"> • ORR, including Complete Response (CR) or Partial Response (PR) | <ul style="list-style-type: none"> • FSI Q1 12 • Est completion date Q4 18 • Est external communication beyond planning horizon |
| Adults with relapsed or refractory B-cell malignancies | Phase I/II NCT00983619 | N = 193 | <ul style="list-style-type: none"> • Arm A: MEDI-551 IV dose escalation study and expansion (FL/CLL/DLBCL/MM) • Arm B: Medi-551 IV dose escalation and expansion (CLL) • Arm C: MEDI-551 IV dose escalation and expansion with Rituximab (DLBCL) • Arm D: MEDI-551 IV (CD20 refractory DLBCL) | <ul style="list-style-type: none"> • MTD and efficacy • Safety and tolerability • Clinical activity of MEDI-551 | <ul style="list-style-type: none"> • FSI Q2 10 (Arm A) • FSI Q2 14 (Amended Arms B – D) • Est completion date Q1 18 • Est external communication beyond planning horizon |
| Adults with relapsed or refractory B-cell malignancies | Phase I NCT01957579 | N = 18 | <ul style="list-style-type: none"> • Dose-escalation study IV <p>Conducted in Japan</p> | <ul style="list-style-type: none"> • MTD and efficacy | <ul style="list-style-type: none"> • FSI Q2 11 • Est completion date Q4 14 • Est external presentation ASH Q4 14 |
| Adults with Relapsed/Refractory Aggressive B-cell Lymphomas | Phase I/II NCT02271945 | N = 38 | <ul style="list-style-type: none"> • MEDI-551 and MEDI0680 (AMP-514) IV <p>Open Label Study</p> | <ul style="list-style-type: none"> • MTD and efficacy • Safety and tolerability • Clinical activity of MEDI55-in combination with MEDI0680 | <ul style="list-style-type: none"> • FSI Q4 14 • Est completion date Q2 19 • Est external communication beyond planning horizon |

Immuno-oncology portfolio

Monotherapy early development programme

| Compound | Patient Population | Phase Study | # of Patients | Design | Endpoint(s) | Status |
|---------------------|--|-------------------------|---------------|--|---|--|
| PD-1 (MEDI0680) | Solid tumours | Phase Ia NCT02013804 | N = 72 | <ul style="list-style-type: none"> Dose Escalation (3+3) & Expansion Study Study amended to explore Q2W schedule and doses > 10mg/kg | <ul style="list-style-type: none"> Safety and tolerability | <ul style="list-style-type: none"> FSI Q4 13 LSI Q2 15 (escalation) LSI Q1 16 (expansion) Est. completion date Q1 16 Est external presentation ASCO Q2 15 |
| PD-L1 (MEDI4736) | NSCLC, SCCHN HCC, pancreas, TNBCBC, gastro- esophageal, uveal melanoma, cutaneous melanoma, bladder, ovarian, GBM, SCLC, HPV/EBV+ anogenital, nasopharyngeal, MSI-High tumors | Phase I NCT01693562 | N = 762 | <ul style="list-style-type: none"> Dose Escalation: 5 cohorts at Q2W and 1 cohort at Q3W Dose Expansion: 16 tumor type cohorts at the Q2W MTD defined during dose escalation <p>Global study – 8 countries</p> | <ul style="list-style-type: none"> Safety Optimal biologic dose Secondary endpoints include PK, immunogenicity and antitumor activity | <ul style="list-style-type: none"> FSI Q3 12 LSI Q2 15 Est completion Q2 16 Est external presentations Q2 15 (ASCO) Further potential update Q3 15 (ESMO) |
| PD-L1 (MEDI4736) | Myelodysplastic syndrome | Phase I NCT02117219 | N = 70 | <p>Dose-escalation and dose-expansion study</p> <ul style="list-style-type: none"> ARM 1: MEDI4736 IV | <ul style="list-style-type: none"> Safety and tolerability Secondary endpoints include duration of response, progression free survival and overall survival | <ul style="list-style-type: none"> FSI Q2 14 LSI Q2 15 (40 pts) LSI Q4 15 (70 pts) Est completion date Q1 16 Est external presentation ASCO Q2 15 |



Anti-PD-L1 (MEDI4736) + Anti-CTLA-4 (tremelimumab)

Solid tumours development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--------------------------------|---------------|--|---|--|
| NSCLC (Immunotx naïve and Immunotx pretreated patient cohorts) | Phase Ib NCT02000947 | N = 208 | <ul style="list-style-type: none"> • Dose Escalation: minimum 5 cohorts exploring various treme Q4W and MEDI4736 IV Q4W dose combinations, higher dose levels and alternate Q2 schedule added with amendment • Dose Expansion: MTD for the combination in escalation to be explored in expansion <p>North American study centers, exploration of 1-2 ex-US countries for expansion</p> | <ul style="list-style-type: none"> • Safety • Optimal biologic dose for the combination • Secondary endpoints include Antitumour activity, PK and immunogenicity | <ul style="list-style-type: none"> • FSI Q4 13 • LSI Q3 15 • Est completion date Q1 17 • Est external presentation ASCO Q2 15 |
| Soft tissue sarcoma (STS), triple-negative breast cancer (TNBC), Bladder, small-cell lung cancer (SCLC), HPV+ anogenital cancers [Basket study] | Phase I NCT02261220 | N = 210 | <ul style="list-style-type: none"> • Dose Exploration: 2 cohorts exploring various Q4W treme and MEDI4736 dose combinations and 2 cohorts exploring various Q2W treme and MEDI4736 dose combinations • Dose Expansion: MTD for the combination in escalation to be explored in expansion cohorts specific for each of 5 tumour types <p>US-only study centers</p> | <ul style="list-style-type: none"> • Safety & tolerability • Optimal biologic dose for the combination • Secondary endpoints include Antitumour activity, PK/PD and immunogenicity | <ul style="list-style-type: none"> • FSI Q4 14 • LSI Q1 16 • Est completion date Q1 17 • Est external presentation ESMO Q3 15 (early data TBD) |
| SCCHN | Phase I NCT02262741 | N = 152 | <ul style="list-style-type: none"> • Cohort A: treatment-naïve, PD-L1+, combo tx • Cohort B: treatment-naïve, PD-L1-, combo tx • Cohort C: 2L-4L, PD-L1+, combo tx • Cohort D: 2L-4L, PD-L1+, treme only <p>North American study centers only</p> | <ul style="list-style-type: none"> • Safety & tolerability • Secondary endpoints include OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers | <ul style="list-style-type: none"> • FSI Q4 14 • LSI Q1 16 • Est completion date Q1 17 • Est external presentation ASCO Q2 15 |



Anti-PD-L1 (MEDI4736) + dabrafenib/trametinib (GSK)

Melanoma development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--------------------------------------|---------------|--|--|---|
| Metastatic or unresectable melanoma BRAF mutation+ (Cohort A) BRAF Wild Type (Cohorts B&C) | Phase I/II NCT02027961 | N = 69 | Dose Escalation: <ul style="list-style-type: none"> • Cohort A – dabrafenib 150mg BiD/ trametinib 2mg QD/ MEDI4736 IV • Cohort B – trametinib 2mg QD/ MEDI4736 IV • Cohort C – trametinib 2mg QD/ MEDI4736 IV Dose Expansion: <ul style="list-style-type: none"> • Each cohort will be expanded at the MTD to enroll a total of 20 subjects per cohort Global study – 2 countries | <ul style="list-style-type: none"> • Safety • Optimal biologic dose for the combination • Secondary endpoints include Objective Response and Disease Control, Duration of Response, Progression-free Survival and Overall Survival, Pharmacokinetics and immunogenicity | <ul style="list-style-type: none"> • FSI Q4 13 • LSI Q4 15 • Est completion date Q4 16 • Est external communication beyond planning horizon |



Anti-PD-L1 (MEDI4736) + *Iressa* (gefitinib)

NSCLC development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|-----------------------------------|---------------|--|---|---|
| NSCLC (Escalation phase) EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase) | Phase I NCT02088112 | N = 47 | Escalation phase Standard 3+3 design with 28 days DLT period • Gefitinib (QD) + MEDI4736 IV Expansion phase • Gefitinib (QD) + MEDI4736 IV recommended dose Study to be conducted in US and Korea | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • FSI Q1 14 • LSI Q1 15 • Est completion date Q4 17 • Est external communication beyond planning horizon |



Anti-PD-L1 (MEDI4736) + Anti-PD-1 (MEDI0680)

Advanced malignancies development programme

| Patient Population | Phase Study | # of Patients | Design | Endpoint(s) | Status |
|-----------------------|------------------------|---------------|--|---|--|
| Advanced malignancies | Phase I NCT02118337 | N = 130 | Dose-escalation phase <ul style="list-style-type: none">• MEDI4736 IV + MEDI0680 IV Dose-expansion phase at selected dose from dose-escalation phase <ul style="list-style-type: none">• MEDI4736 IV + MEDI0680 IV recommended dose | <ul style="list-style-type: none">• Safety• Determination of MTD <ul style="list-style-type: none">• Secondary endpoints include tumour response such as objective response rate, disease control rate, progression-free survival, duration of response, overall survival, immunogenicity, pharmacokinetics, pharmacodynamics | <ul style="list-style-type: none">• FSI Q2 14• LSI Q3 15• Est completion date Q4 16• Est external presentation ASCO Q2 15 |



Murine Anti-OX40 (MEDI6469) + combinations

Advanced malignancies development programme

| Patient Population | Phase Study | # of Patients | Design | Endpoint(s) | Status |
|-----------------------|---------------------------|---------------|---|---|--|
| Advanced malignancies | Phase I/II NCT02205333 | N = 212 | Dose-escalation phase <ul style="list-style-type: none">• MEDI6469 IV monotherapy• MEDI6469 IV + MEDI4736 IV• MEDI6469 IV + tremelimumab IV• MEDI6469 IV + rituximab IV | <ul style="list-style-type: none">• Determination of MTD• Safety • Secondary endpoints include antitumor activity, pharmacokinetics, and immunogenicity | <ul style="list-style-type: none">• FSI Q3 14• LSI Q2 16• Est completion date Q2 16• Est external communication beyond planning horizon |



OX40 agonist (MEDI6383)

Advanced malignancies development programme

| Patient Population | Phase Study | # of Patients | Design | Endpoint(s) | Status |
|-----------------------|------------------------|---------------|--|---|--|
| Advanced malignancies | Phase I NCT02221960 | N = 116 | Dose-escalation phase • MEDI6383 IV | <ul style="list-style-type: none">• Safety• Determination of MTD • Secondary endpoints include preliminary antitumor activity, pharmacokinetics, Biomarker activity, and immunogenicity | <ul style="list-style-type: none">• FSI Q3 14• LSI Q3 16• Est completion date Q4 16• Est external communication beyond planning horizon |



Oncology biologics early development

Solid tumors development programme

| Compound | Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--------------------------------|---|----------------------------|---------------|--|---|---|
| Anti-Ang2 mAb (MEDI3617) | Solid tumors and ovarian cancer | Phase I NCT01248949 | N = 16 | • MEDI3617 + bevacizumab dose escalation, administered Q3W, IV (US only) | • Safety and tolerability | • FSI Q4 2010 • Est completion date Q3 16 • Est external presentation beyond planning horizon |
| | | | 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 = 15-120 | • MEDI3617 + bevacizumab dose expansion in recurrent malignant glioma | | |
| Anti-IGF ligand mAb (MEDI-573) | Patients with HR+ HER2-, 1 st line, metastatic breast cancer taking aromatase inhibitors | Phase I/III NCT01446159 | N = 176 | • ARM 1: MEDI-573 IV and Aromatase Inhibitor • ARM 2: Aromatase Inhibitor alone Open label study | • Progression Free Survival • Retrospective evaluation of predictive biomarker +ve subgroups | • FSI Q2 11 • LSI Q2 13 • Est completion date Q4 15 • Est external presentation 2015 |



Oncology biologics early development

Solid tumours development programme

| Compound | Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|-------------------------------------|---|--|---|--|---|--|
| Anti-CEA BiTE mAb (MEDI-565) | <p>Adults with gastrointestinal (GI) adenocarcinoma with no available standard or curative treatments.</p> <p>Refractory pancreatic, colorectal and gastro-esophageal cancers</p> | <p>Phase I</p> <p>NCT01284231</p> <p>Partnered</p> | <p>N = 51 max</p> <p>N = 60 max, 20 in each cohort</p> | <ul style="list-style-type: none"> • Dose-escalation (3+3), IV • Dose expansion study, IV | <ul style="list-style-type: none"> • MTD and safety profile | <ul style="list-style-type: none"> • FSI Q4 10 • Est completion date Q3 17 • Estimated external presentation beyond planning horizon |
| Anti-DLL4 mAb (MEDI0639) | Adults with advanced solid tumors including SCLC | <p>Phase I</p> <p>NCT01577745</p> | <p>N = up to 28</p> <p>N = up to 32</p> | <ul style="list-style-type: none"> • Dose-escalation study (3+3); IV • Combination dose-escalation and expansion study; IV | <ul style="list-style-type: none"> • MTD and safety profile • MTD and safety profile in combination | <ul style="list-style-type: none"> • FSI Q2 12 • LSI Q4 15 • Est completion date Q4 16 • Est external presentation beyond planning horizon |



Tralokinumab (anti-IL-13)

IPF development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|-------------------------|---------------|---|--|---|
| Adults with Idiopathic Pulmonary Fibrosis | Phase II NCT01629667 | N = 186 | <ul style="list-style-type: none"> • ARM 1: Tralokinumab high dose IV • ARM 2: Tralokinumab low dose IV • ARM 3: Placebo IV <p>High dose: low dose: placebo (1:1:1) Global study – 6 countries</p> | <ul style="list-style-type: none"> • Change from baseline in percent-predicted forced vital capacity at week 72 <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • No. of patients with disease progression • Safety and tolerability • Tralokinumab serum concentration | <ul style="list-style-type: none"> • FSI Q4 12 • Est completion date Q1 17 • Est external presentation beyond planning horizon |
| Japanese Adults with Idiopathic Pulmonary Fibrosis | Phase II NCT02036580 | N = 20 | <p><u>Cohort 1:</u></p> <ul style="list-style-type: none"> • ARM 1: Tralokinumab high dose IV • ARM 2: Placebo IV <p><u>Cohort 2 :</u></p> <ul style="list-style-type: none"> • ARM 1: Tralokinumab low dose IV • ARM 2: Placebo IV <p>8:2 randomisation in both cohorts Japan only study</p> | <ul style="list-style-type: none"> • Safety and tolerability <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • Tralokinumab serum concentration • Immunogenicity | <ul style="list-style-type: none"> • FSI Q1 14 • Est completion date Q4 15 • Est external presentation beyond planning horizon |



Anti-IL-17RA (brodalumab)

Asthma development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|-------------------------|---------------|---|--|---|
| Moderate to severe inadequately controlled high reversibility asthma | Phase II NCT01902290 | N = 566 | <ul style="list-style-type: none">• ARM 1: 210 mg brodalumab SC• ARM 2: placebo SC | <ul style="list-style-type: none">• Change in ACQ at wk 24 | <ul style="list-style-type: none">• FSI Q2 13• Est completion date Q1 15 |



Anti-TSLP (MEDI9929)

Asthma development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--|---------------|--|--|---|
| Adult subjects with inadequately controlled, severe asthma | Phase II PATHWAY NCT02054130 Partnered | N = 552 | <ul style="list-style-type: none">• ARM 1: Placebo• ARM 2: Low dose MEDI9929 SC• ARM 3: Medium dose MEDI9929 SC• ARM 4: High dose MEDI9929 SC | <ul style="list-style-type: none">• Reduction in the annualized asthma exacerbation rate (AER) measured at Week 52 | <ul style="list-style-type: none">• FSI Q4 13• LSI Q3 15• Est completion date Q4 16• Est external presentation beyond planning horizon |



Mavrimumab (anti-GMCSF)

RA development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|--|----------------------|---|---|--|
| RA patients with an inadequate response to DMARDs | Phase II EARTH Explorer 1 NCT01706926 | N = 326 (final) | <ul style="list-style-type: none"> • ARM 1: Mavrimumab low dose SC • ARM 2: Mavrimumab medium dose SC • ARM 3: Mavrimumab high dose SC • ARM 4: Placebo <p>Global study (ex-US) on MTX background; 16 countries</p> | <ul style="list-style-type: none"> • DAS28 response at wk12 • ACR 20 at wk 24 | <ul style="list-style-type: none"> • FSI Q3 12 • LSI Q2 13 • Completed Q1 14 • Est external presentation ACR Q4 14 |
| 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 NCT01715896 | N = 138 (final) | <ul style="list-style-type: none"> • ARM 1: Mavrimumab SC • ARM 2: golimumab <p>Global study (ex-US) on MTX background; 17 countries</p> | <ul style="list-style-type: none"> • ACR 20/50/70 at wk 24 • DAS28 remission • Function (HAQ-DI) | <ul style="list-style-type: none"> • FSI Q1 13 • LSI Q2 14 • Est completion date Q4 14 • Est external presentation beyond planning horizon |
| Eligible RA patients from Explorer 1 & 2 | Phase II EARTH Explorer X NCT01712399 | N = 400 Projected | <ul style="list-style-type: none"> • ARM 1: Mavrimumab SC <p>Open label extension of Explorer 1 & 2</p> <p>Global study (ex-US) on MTX background; 23 countries</p> | <ul style="list-style-type: none"> • Safety and exploratory efficacy | <ul style="list-style-type: none"> • FSI Q1 13 • OLE, Est completion date Q1 20 • Est external presentation beyond planning horizon |
| Healthy Japanese Subjects | Phase I NCT02213315 | N = 24 (final) | <ul style="list-style-type: none"> • ARM 1: Mavrimumab medium dose SC • ARM 2: Mavrimumab high dose SC • ARM 3: Placebo SC <p>UK Study; Japanese subjects</p> | <ul style="list-style-type: none"> • Pharmacokinetic profile • Safety and tolerability | <ul style="list-style-type: none"> • FSI Q3 14 • LSI Q3 14 • Est completion date Q4 14 • Est external presentation 2015 |



Sifalimumab (anti-interferon α)

SLE development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|------------------------------|-------------------------|-----------------|--|--|--|
| Moderate-severe SLE patients | Phase II NCT01283139 | N = 433 (final) | <ul style="list-style-type: none">• ARM 1: 200 mg IV MEDI-545 Q2W for 4 wks then Q4W for 44 wks• ARM 2: 600 mg IV MEDI-545 Q2W for 4 wks then Q4W for 44 wks• ARM 3: 1200 mg IV MEDI-545 Q2W for 4 wks then Q4W for 44 wks• ARM 4: placebo IV Q2W for 4 wks then Q4W for 44 wks | <ul style="list-style-type: none">• Proportion of subjects achieving a response in an SLE responder index at 12 months | <ul style="list-style-type: none">• FSI Q1 11• Est completion Q4 13• Est external presentation ACR Q4 14 |
| SLE, DM or PM patients | Phase II NCT00979654 | N = 260 | <ul style="list-style-type: none">• 600 mg IV Medi-545 <p>Open label study</p> | <ul style="list-style-type: none">• Evaluate long-term safety and tolerability of multiple IV doses of MEDI-545 | <ul style="list-style-type: none">• FSI Q3 10• Est completion Q1 15• Est external presentation beyond planning horizon |



Anifrolumab (anti-type I IFN receptor)

SLE development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|------------------------------|-------------------------|-----------------|--|---|---|
| Moderate-severe SLE patients | Phase II NCT01438489 | N = 307 (final) | <ul style="list-style-type: none"> • ARM 1: 300 mg IV MEDI-546 Q4W for 48 weeks • ARM 2: 1000 mg IV MEDI-546 Q4W for 48 weeks • ARM 3: placebo IV Q4W for 48 weeks | <ul style="list-style-type: none"> • Response in SLE responder index at 6 months | <ul style="list-style-type: none"> • FSI Q1 12 • Est completion date Q3 14 • Est external presentation 2015 |
| Moderate-severe SLE patients | Phase II NCT01753193 | N = 240 | <ul style="list-style-type: none"> • ARM 1: MEDI-546, IV Q4W for 104 weeks | <ul style="list-style-type: none"> • Open-label extension to evaluate long-term safety and tolerability | <ul style="list-style-type: none"> • FSI Q1 13 • Est completion date Q3 17 • Est external presentation beyond planning horizon |
| Japanese SLE patients | Phase II NCT01559090 | N = 17 | <ul style="list-style-type: none"> • ARM 1: <ul style="list-style-type: none"> • Stage I: 100mg IV MEDI-546, single dose and multiple doses Q4W for 48 wks. • Stage II: 300mgIV, multiple doses Q4W for 104 wks • ARM 2: <ul style="list-style-type: none"> • Stage I: 300mg IV MEDI-546, single dose and multiple doses Q4W for 48 wks. • Stage II: 300mgIV, multiple doses Q4W for 104 wks • ARM 3: <ul style="list-style-type: none"> • Stage I: 1000mg IV MEDI-546, single dose and multiple doses Q4W for 48 wks. • Stage II: 1000mgIV, multiple doses Q4W for 104 wks | <ul style="list-style-type: none"> • Safety profile of MEDI-546: adverse events, vital signs, clinical laboratory assessments and ECGs | <ul style="list-style-type: none"> • FSI Q2 12 • Est completion date Q3 14 • Est external presentation ACR Q4 14 |



Anti-B7RP-1 (MEDI5872)

SLE development programme

| Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|--|---|---------------|--|---|---|
| SLE and lupus related inflammatory arthritis | Phase I NCT01683695 Partnered | N = 42 | Dose escalation study: • ARM 1: MEDI5872 SC • AMR 2: placebo SC Global study – 8 countries | <ul style="list-style-type: none">• Safety and tolerability• Lupus Arthritis Response Rate | <ul style="list-style-type: none">• FSI Q2 12• LSI Q2 15• Est. Completion date Q2 16• Est external publication beyond planning horizon |



Infectious diseases biologics early development

Phase I/II clinical development programmes

| Compound | Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|------------------------------------|--------------------|------------------------------------|---------------|---|---|---|
| Anti-Staph AT (MEDI4893) | Healthy Adults | Phase II EudraCT 2014-001097-34 | N = 462 | <ul style="list-style-type: none"> Placebo-controlled, single-dose, dose-ranging Route of administration: intravenous | <ul style="list-style-type: none"> Efficacy and Safety | <ul style="list-style-type: none"> FSI October 2014 External presentation planned for 2015 |
| RSV sF+GLA-SE (MEDI7510) | Adults ≥ 60 yrs | Phase I NCT02115815 | N = 144 | <ul style="list-style-type: none"> ARM 1: MEDI7510 IM ARM 2: RSV sF IM ARM 3: Placebo IM | <ul style="list-style-type: none"> Safety and tolerability Humoral and cell-mediated immune responses | <ul style="list-style-type: none"> FSI Q2 14 Est completion date Q3 14 Est. external presentation Q4 14 |
| Anti-RSV mAb-YTE (MEDI8897) | Healthy Adults | Phase Ia NCT02114268 | N = 136 | <ul style="list-style-type: none"> ARM 1: MEDI8897 IV & IM ARM 2: Placebo | <ul style="list-style-type: none"> Evaluate Safety, Tolerability, PK and ADA | <ul style="list-style-type: none"> FSI Q2 14 Dosing Complete External presentations International RSV Symposium Q4 14 |
| Anti-Pseudomonas a. mAb (MEDI3902) | Healthy Adults | Phase I NCT02255760 | N = 40 | <ul style="list-style-type: none"> Randomized, Double-blind, Placebo-Controlled, Dose-Escalation Study Route of administration: intravenous | <ul style="list-style-type: none"> Evaluate the Safety, Tolerability, and Pharmacokinetics of | <ul style="list-style-type: none"> FSI Q3 14 LSI Q1 15 Est completion date Q2 15 External presentation planned for 2015 |



Vaccines biologics early development

Phase I/II clinical development programmes

| Compound | Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|---|---|---------------|---|--|---|
| LAIV RSV Paediatric Vaccine (MEDI-559) | Healthy 6-24 mo prevention of RSV disease in infants | Phase I/IIa NCT00767416 | N = 116 | <ul style="list-style-type: none"> • Randomized, Double-Blind, Placebo-Controlled Study • Route of administration: intranasal | <ul style="list-style-type: none"> • Evaluate the Safety, Tolerability, Immunogenicity and Viral Shedding | <ul style="list-style-type: none"> • Completed • MEDI-559 was found to be biologically active and immunogenic in the 6-24month seronegative pediatric population. An imbalance in MA-LRIs was observed and warrants expanded safety studies |
| Pandemic flu library (MEDI-550) | Healthy adults | Phase I NCT01175122 NCT00922259 NCT00516035 NCT00853255 NCT01674205 NCT00110279 NCT01443663 NCT00347672 NCT00488046 NCT01534468 NCT00722774 NCT00734175 NCT00380237 Partnered | Varies | <ul style="list-style-type: none"> • Administration of live attenuated influenza virus vaccine for the following strains: H2N2, H2N3, H5N1, H6N1, H7N3, H7N7, H9N2 (separate studies for each strain) <p>Nasal administration</p> <p>US only</p> | <ul style="list-style-type: none"> • Safety and Immunogenicity | <ul style="list-style-type: none"> • Study Starts: 2005-2012 • Primary Completion Dates: 2005-2012 |



Neuroscience biologics early development

Phase I development programmes

| Compound | Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|----------------------------------|--|-----------------------------|---------------|---|--|---|
| Anti-amyloid beta mAb (MEDI1814) | Alzheimers Disease & Healthy Elderly | Phase I NCT02036645 | N = 121 | <ul style="list-style-type: none"> SAD & MAD Up to 10 iv cohorts are planned vs placebo 2 SC cohorts are planned vs placebo <p>US only</p> | <ul style="list-style-type: none"> Safety, tolerability | <ul style="list-style-type: none"> FSI Q2 14 LSI Q2 16 Est. Completion date Q4 16 Est. external presentation beyond planning horizon |
| Anti-CD19 mAb (MEDI-551) | Adults with Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders (NMO/NMOSD) | Phase II/III NCT02200770 | N = 212 | <ul style="list-style-type: none"> ARM 1: MEDI-551 IV ARM 2: placebo IV Open-label extension <p>Global study</p> | <ul style="list-style-type: none"> Primary: Time to attack Secondary: Attack rate, safety and tolerability | <ul style="list-style-type: none"> FSI planned Q4 14 LSI Q2 17 Est. completion date Q4 17 Estimated external presentation beyond planning horizon |
| | Adults with Multiple sclerosis | Phase I NCT01585766 | N = 28 | <ul style="list-style-type: none"> SAD (IV/SC) <p>Global study</p> | <ul style="list-style-type: none"> Safety, PK | <ul style="list-style-type: none"> FSI Q2 12 LSI Q3 14 Est. completion date Q1 15 External data presentation planned in 2015 |
| Anti-CD40L (MEDI4920) | Healthy Adults | Phase I NCT02151110 | N = 56 | <ul style="list-style-type: none"> Dose-escalation study, single IV dose | <ul style="list-style-type: none"> Safety, tolerability, and pharmacokinetics, anti-drug antibody, inhibition of T-cell dependent antibody response | <ul style="list-style-type: none"> FSI Q2 14 Est completion date Q2 15 Estimated external presentation beyond planning horizon |



Gastrointestinal biologics early development

Phase I/II development programmes

| Compound | Patient Population | Phase Study | # of patients | Design | Endpoint(s) | Status |
|---|--|--|-----------------|---|--|---|
| Anti- α 4 β 7 mAb (MEDI7183) | Moderate to Severe Ulcerative Colitis | Phase II NCT01694485 Partnered | N = 360 | <ul style="list-style-type: none"> • ARM 1: MEDI7183 dose level 1, SC • ARM 2: MEDI7183 dose level 2, SC • ARM 3: MEDI7183 dose level 3, SC • ARM 4: MEDI7183 dose level 4, SC • ARM 5: Matching Placebo, SC Global study - 19 countries | Remission at week 8 (Mayo Score) | <ul style="list-style-type: none"> • FSI Q4 12 • Enrollment suspended due to logistical issues re-started Q4 13 • LSI Q4 14 • Est completion date Q1 15 • Est external presentation 2016 |
| | Moderate to Severe Crohn's Disease | Phase II NCT01696396 Partnered | N = 252 | <ul style="list-style-type: none"> • ARM 1: MEDI7183 low dose, SC • ARM 2: MEDI7183 medium dose, SC • ARM 3: MEDI7183 high dose, SC • ARM 4: Matching Placebo, SC Global study - 12 countries | Remission at week 8 (CDAI < 150) | <ul style="list-style-type: none"> • FSI Q4 12 • Enrollment suspended due to logistical issues re-started Q4 13 • LSI Q4 14 • Est completion date Q2 15 • Est external presentation 2016 |
| | Japanese subjects with moderate to severe Ulcerative Colitis | Phase II NCT01959165 Partnered | N = 48 | <ul style="list-style-type: none"> • ARM 1: MEDI7183 low dose, SC • ARM 2: MEDI7183 medium dose, SC • ARM 3: MEDI7183 high dose, SC • ARM 4: Matching Placebo, SC | Remission at week 8 (Mayo Score) | <ul style="list-style-type: none"> • FSI Q4 13 • LSI Q1 15 • Est completion date Q2 15 • Est external presentation 2016 |
| Anti-IL-23 mAb MEDI2070 | Patients with Moderate to Severe Crohn's Disease | Phase II NCT01714726 Partnered | N = 121 (final) | <ul style="list-style-type: none"> • ARM 1: MEDI2070, IV (SC for OLE) • ARM 2: Placebo, IV Global study - 9 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 | <ul style="list-style-type: none"> • FSI Q1 13 • LSI Q1 14 • Est completion date Q2 14 • Est external presentation Q1 15 |



AstraZeneca Clinical Programmes Summary

List of abbreviations

| | |
|--------------|---|
| TOC | Test of Cure |
| MITT | Modified Intent-To-Treat population |
| cMITT | Clinical Modified Intent-To-Treat population |
| mMITT | Microbiological Modified Intent-To-Treat population |
| CE | Clinically Evaluable |
| SAD | Single Ascending Dose Study |
| MAD | Multiple Ascending Dose Study |
| QD | Once Daily |
| BiD | Twice Daily |
| TiD | Three Times a Day |
| Q2W | Every Other Week |
| Q3W | Every Three Weeks |
| Q4W | Every Four Weeks |
| Q8W | Every Eight Weeks |
| XR | Extended Release |
| IR | Immediate Release |
| SC | Sub-cutaneous |
| IV | Intra-venous |
| IM | Intra-muscular |

| | |
|----------------|---|
| MTD | Maximum Tolerated Dose |
| PFS | Progression Free Survival |
| ORR | Objective Response Rate |
| OS | Overall Survival |
| FEV | Forced Expiratory Volume |
| DLT | Dose Limiting Toxicity |
| AEs | Adverse Events |
| FSI | First Subject In |
| LSI | Last Subject In |
| OLE | Open Long Term Extension |
| MDI | Metered Dose Inhaler |
| ICS | Inhaled Corticosteroid |
| LABA | Long Acting Beta Agonist |
| LAMA | Long Acting Muscarinic Agonist |
| MTX | Methotrexate |
| ASA | Acetylsalicylic Acid |
| PARP | Poly ADP ribose polymerase |
| HIF-PHI | Hypoxia-inducible factor prolyl hydroxylase |

