AstraZeneca

Clinical Programmes Summary

2Q 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 June 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.

AstraZeneca

2Q 2014: 4 new NME pivotal study starts contributing to growing late stage pipeline

Pivotal study starts in 2Q 2014

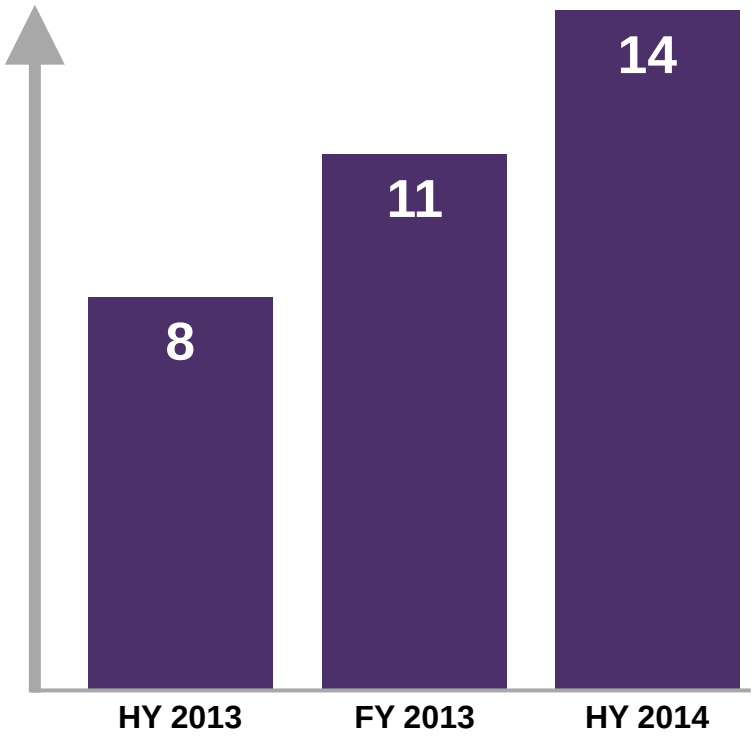
NMEs

- roxadustat (HIF) CKD & ESRD
- tremelimumab (CTLA-4) mesothelioma
- AZD9291 (EGFR) 2L NSCLC
- PD-L1 (MEDI4736) NSCLC

LEs

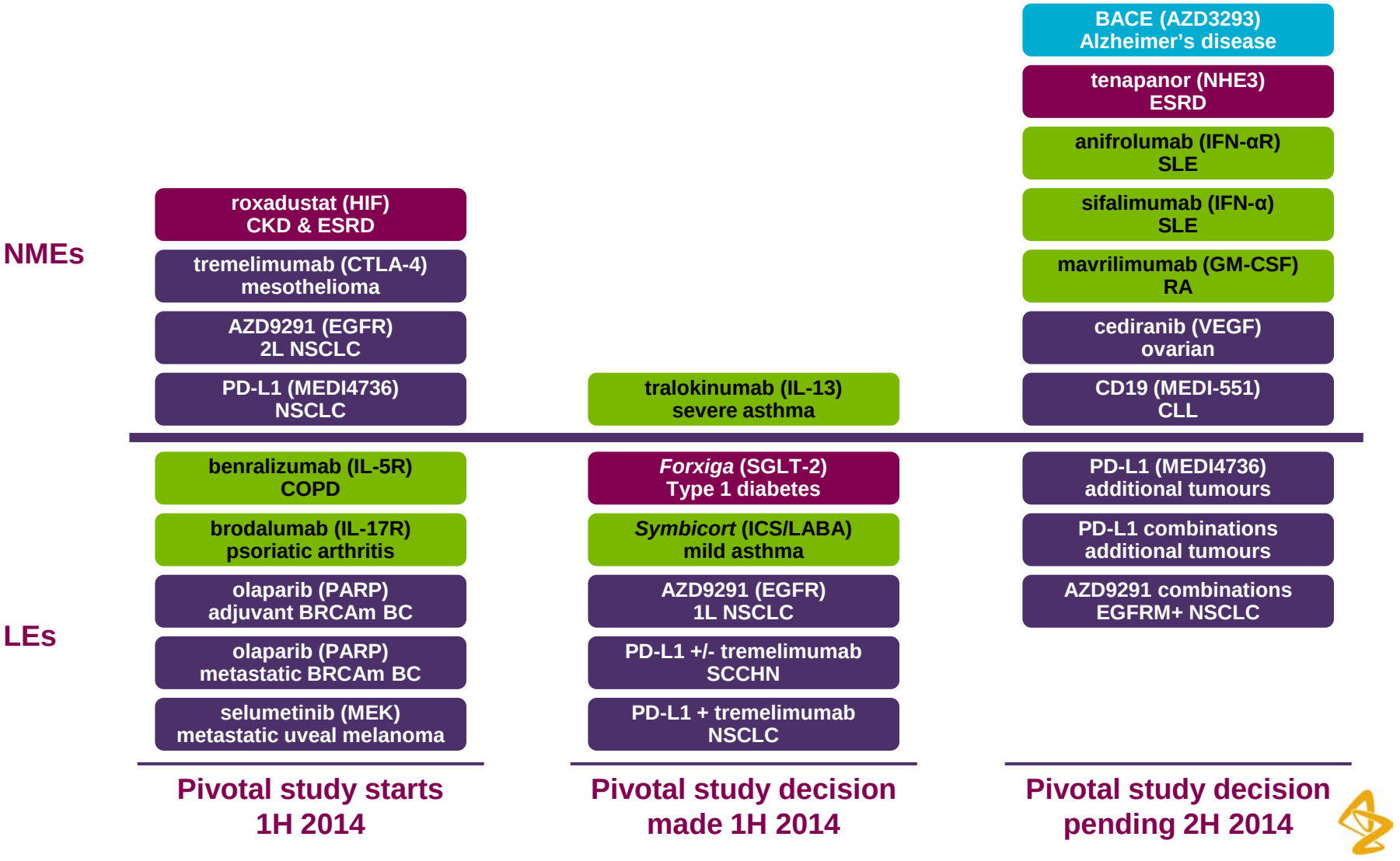
- benralizumab (IL-5R) COPD
- olaparib (PARP) adjuvant BRCAm BC

Number of NMEs in pivotal studies



Oncology | RIA | CVMD

2014: Continued strong momentum in late stage pipeline



Oncology | RIA | CVMD | Neuroscience

Movements since Q1 2014 update

New to Phase I	New to Phase II	New to Pivotal Study	New to Registration
NMEs **MCH (AZD1979)** obesity **Androgen (AZD5312)** prostate cancer **CD19 (MEDI-551) + rituximab** haems **Amyloidβ (MEDI1814)** Alzheimer's **PD-L1 (MEDI4736) + Iressa** EGFR M+ NSCLC **PD-L1 (MEDI4736) + PD-1 (MEDI0680)** solid tumours **CD40L (MEDI4920)** Primary Sjögren's syndrome **RSV sF+GLA –SE (MEDI7510)** RSV prophylaxis **RSV Mab YTE (MEDI8897)** RSV prophylaxis **Tremelimumab (CTLA-4) + Iressa** EGFR M+ NSCLC **Added back to pipeline** **SGRM (AZD7594)** asthma, COPD	**NMEs** **IFNβ (AZD9412) (SNG001)¥** asthma, COPD **TSLP (MEDI9929)** asthma **LABA/LAMA/ICS (PT010)** COPD **Volitinib (MET)** solid tumours	**NMEs** **AZD9291** EGFR T790M+ NSCLC **PD-L1 (MEDI4736)** Stage III NSCLC **Roxadustat (HIF)** anaemia in CKD/ESRD **Tremelimumab (CTLA-4)** mesothelioma **Additional indications** **Benralizumab (IL-5R)** COPD **PD-L1 (MEDI4736)** 3L NSCLC **olaparib** PARP adjuvant breast cancer	
Removed from Phase I	**Removed from Phase II**	**Removed from Phase III**	**Removed from Registration**
NMEs **CXCR2 (AZD4721)** COPD **HtN9 vaccine (MEDI9287)** avian flu	**NMEs** **CXCR2 (AZD5069)** asthma **IL-1R (MEDI8968)** COPD, HS **Additional indications** **Tenapanor (NHE3)** fluid retention		**Epanova (US)*** hypertriglyceridaemia

¥ New business development; *Approved Q2 2014

A growing and accelerating late stage pipeline

Phase 1
35 New Molecular Entities

Small molecule

- **PIM (AZD1208)** haems
- **Androgen (AZD5312)** prostate
- **ATR (AZD6738)** CLL, H&N
- **PI3Kβδ (AZD8186)** solid tumours
- **STAT3 (AZD9150)** haems + solids
- **TLR9 (AZD1419)** asthma
- **SGRM (AZD7594)** asthma, COPD
- **p38 inhibitor (AZD7624)** COPD
- **TLR7 agonist (AZD8848)** asthma
- **MCH (AZD1979)** obesity
- **BACE (AZD3293)** Alzheimer's
- **NMDA (AZD6423)** suicidal ideation
- **ATM AVI** BL/BLI SBI
- **GyrAr (AZD0914)** serious infection

Large molecule

- **DLL-4 (MEDI0639)** solid tumours
- **PD-1 (MEDI0680)** solid tumours
- **CEA BiTE (MEDI-565)** GI tumours
- **ANG-2 (MEDI3617)** solid tumours
- **mOX40 (MEDI6469)** solid tumours
- **CD40L (MEDI4920)** Primary Sjögren's Syndrome
- **B7RP1 (MEDI5872)** SLE
- **LCAT (MEDI6012)** ACS
- **Rh-Factor II (MEDI8111)** rauma/bleeding
- **Amyloidβ (MEDI1814)** Alzheimer's
- **MEDI-550** pandemic influenza virus vaccine
- **staph alpha tox. (MEDI4893)** SSI
- **MEDI7510** RSV sF+GLA-SE RSV prevention
- **MEDI8897** RSV Mab YTE passive RSV prophylaxis
- **PRVV (MEDI-559)** Paediatric RSV vaccine

Oncology combinations

- **PD-L1 + dabrafenib + trametinib** melanoma
- **PD-L1 + Iressa** EGFR M+ NSCLC
- **PD-L1 + tremelimumab** solid tumours
- **PD-L1 + PD-1** solid tumours
- **CD-19 + rituximab** haems
- **tremelimumab + Iressa** NSCLC

Phase 2
24 New Molecular Entities

Small molecule

- **WEE-1 (AZD1775)** ovarian, 1L NSCLC
- **TORC ½ (AZD2014)** solid tumours
- **FGFR (AZD4547)** solid tumours
- **AKT (AZD5363)** breast cancer
- **volitinib (MET)** solid tumours
- **MABA (AZD2115)** COPD
- **LABA/LAMA/ICS (PT010)** COPD
- **URAT1 (RDEA3170)** gout
- **Hormone mod. (AZD4901)** PCOS
- **tenapanor (AZD1722)** NHE3 inhibitor ESRD-Pi/CKD
- **MPO (AZD3241)** Multiple System Atrophy
- **H3R (AZD5213)** Tourette's, neuropathic pain
- **Oxazolidinone (AZD5847)** TB
- **BLI/cephalosporin (CXL)** MRSA

Large molecule

- **CD19 (MEDI-551)** CLL, DLBCL
- **IGF (MEDI-573)** metastatic breast cancer
- **anifrolumab** IFNaR SLE
- **AZD9412 (Inhaled βIFN)** asthma, COPD
- **mavrilimumab (GM-CSFR)** rheumatoid arthritis
- **IL-23 (MEDI2070)** Crohn's
- **α4β7 (MEDI7183)** Crohn's, ulcerative colitis
- **TSLP (MEDI9929)** asthma
- **sifalimumab (IFNa)** SLE
- **IL-13 (tralokinumab)** asthma, IPF

Phase 3 / Registration
14 New Molecular Entities

Small molecule

- **AZD9291 (EGFRm+ t790m+)** NSCLC
- **olaparib (PARP)** BRCA ovarian, gastric, breast
- **selumetinib (MEK)** 2L KRAS+ve NSCLC, uveal melanoma, DTC
- **lesinurad (URAT1)** gout
- **LABA/LAMA (PT003)** COPD
- **LAMA (PT001)** COPD
- **roxadustat (HIF)** anaemia CKD/ESRD
- **Movantik (PAMORA)** opioid induced constipation
- **CAZ AVI (BLI/cephalosporin)** SBI

Large molecule

- **PD-L1 (MEDI4736)** NSCLC
- **Moxetumomab (CD22)** HCL
- **tremelimumab (CTLA-4)** mesothelioma
- **brodalumab (IL-17R)** psoriasis, psoriatic arthritis
- **benralizumab (IL-5R)** severe asthma, COPD

New approvals
1 New Molecular Entity

Small molecule

- **Epanova** hypertriglyceridaemia

Large molecule

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Terminations in Q2 2014
AZD5069 (asthma) in Phase 2, MEDI8968 (COPD, HS) in Phase 2, AZD4721 (COPD) in Phase 1, MEDI9287 (avian flu) in Phase 1 (AZD5069 and AZD4721 termination decisions made in July 2014)

Pipeline table as of 30th June 2014

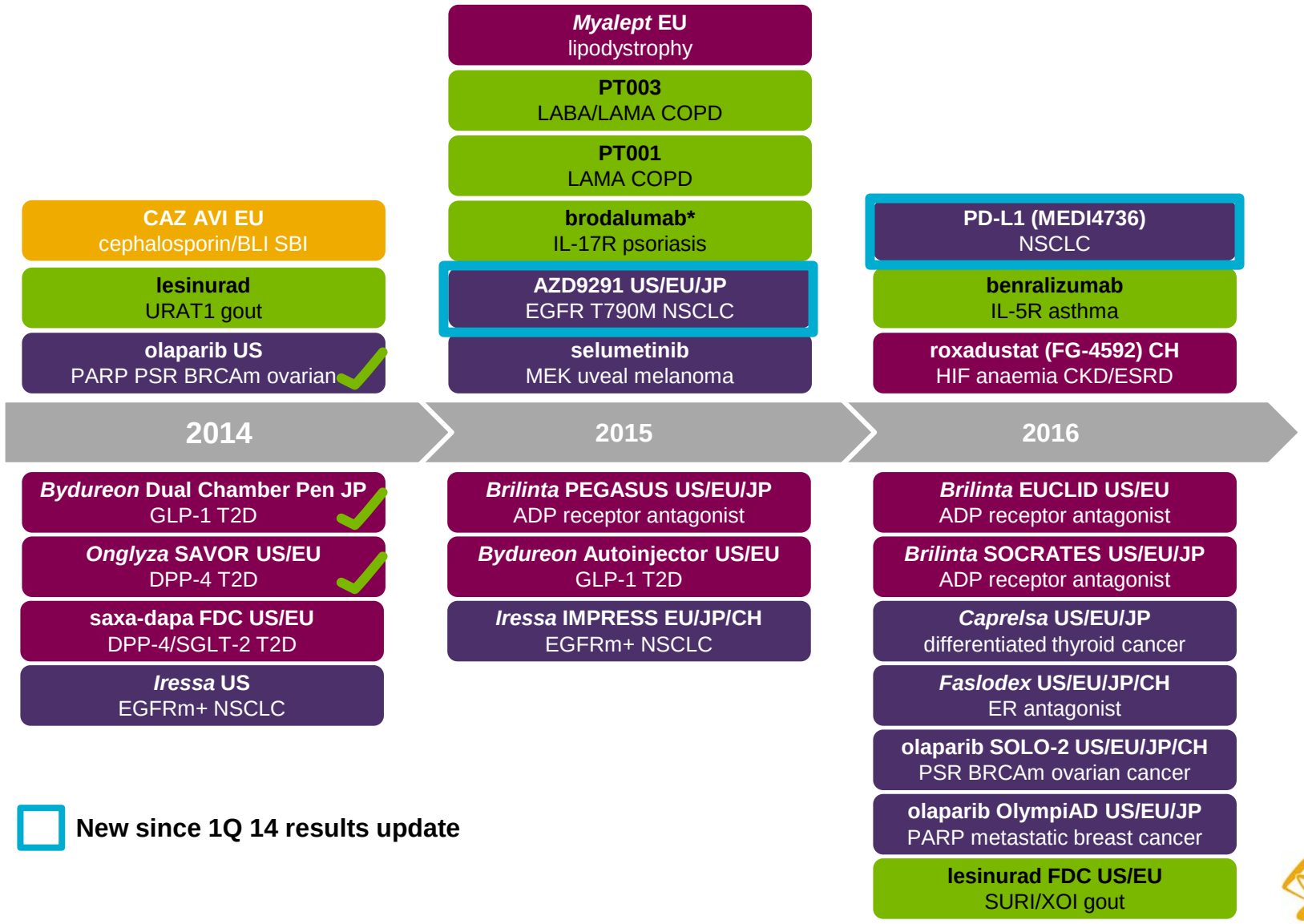
2H 2014: Key data readouts

Compound	Indication	Milestone
lesinurad	gout	Ph III topline results
CAZ AVI	cIAI	Ph III topline results
brodalumab	psoriasis	Ph III topline results
sifalimumab	SLE	Ph IIb (ACR)
mavrilimumab	RA	Ph IIb (ACR)
MEDI4736	solid tumours	Ph I (ESMO)
MEDI4736 + tremelimumab	NSCLC	Ph I (ESMO)
AZD9291	NSCLC	Ph I (ESMO)
AZD3293	Alzheimer's disease	Ph I (CTAD)

2H 2014: Key regulatory milestones

Compound	Indication	Potential milestones
Iressa	EGFRm NSCLC	US filing
Movantik	OIC	US approval (PDUFA 16 Sep 2014)
Movantik	OIC	EU approval
Brilinta	ACS	JP approval
olaparib	PSR BRCAm ovarian cancer	US approval (PDUFA 3 Jan 2015)
Xigduo XR	type 2 diabetes	US approval (PDUFA 29 Oct 2014)
saxagliptin/dapagliflozin FDC	type 2 diabetes	US filing
lesinurad	gout	EU, US filing
CAZ AVI	cIAI	EU filing

Potential NME & LE submissions 2014-16



* Filing is the responsibility of partner

Oncology | RIA | CVMD | Neuroscience | Infection

AstraZeneca

LE development programmes

2Q 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	• **ARM 1**: Ticagrelor 90 mg BiD • **ARM 2:** Ticagrelor 60 mg BiD • **ARM 3:** Placebo BiD *on a background of ASA* Global study – 31 countries	• Composite of CV death, non-fatal MI and non-fatal stroke	• 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	• **ARM 1:** Ticagrelor 90 mg BiD • **ARM 2:** Clopidogrel 75 mg QD *monotherapy trial* Global study – 28 countries	• Composite of CV death, non-fatal MI and ischemic stroke	• FSI Q3 12 • LSI Q1 14 • Est. completion date Q1 16 • Est. external presentation 2016
Patients with Stroke or TIA	**Phase III SOCRATES** NCT01994720	N = 9600	• **ARM 1:** Ticagrelor 90 mg BiD • **ARM 2:** ASA 100mg/day *monotherapy trial* Global study – approx. 32 countries	• Composite of non-fatal stroke, non-fatal MI and all cause death	• 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	• **ARM 1**: Ticagrelor 90 mg BiD • **ARM 2:** Placebo BiD *on a background of ASA if not contra indicated or not tolerated* Global study – approx. 40 countries	• Composite of CV death, non-fatal MI and non-fatal stroke	• FSI Q1 14 • Est. completion date Q1 17 • Est. external presentation beyond planning horizon

Forxiga/Farxiga (SGLT-2 inhibitor)

Type 2 Diabetes development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Typ 2 diabetes mellitus with high risk for CV event	**Phase III/IV DECLARE** **NCT01730534**	N = 17150	• **ARM 1:** Dapagliflozin 10 mg QD + standard of care therapy QD • **ARM 2:** Placebo + standard of care therapy for Type 2 Diabetes Global study – 33 countries	• Time to first event included in the composite endpoint of CV death, MI or ischemic stroke	• FSI Q2 13 • LSI Q2 16 • Est. completion date Q2 19 • Est. external presentation 2020

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 = 740	• **ARM 1:** Saxagliptin 5 mg QD • **ARM 2:** Placebo QD Study in China	Primary: • Mean change from baseline in HbA1C at 24 week Secondary: • The change from baseline at 24 week in 120-minute postprandial plasma glucose (PPG) in response to a meal tolerance	• 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	• **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 Global study – 12 countries	Primary: • Mean change from baseline in HbA1C at 24 week Secondary: • Mean change from baseline in 2h MTT at 24 week	• FSI Q3 12 • LSI Q2 13 • Primary completion date Q1 14 • Targeted as Late Breaking abstract Q2 14 (ADA)
Type 2 Diabetes Mellitus	**Phase III** NCT01619059	N = 280	• **ARM 1:** Saxa 5mg + Dapa 10 mg + Met IR • **ARM 2:** Placebo + Dapa 10 mg + Met IR Global study – 9 countries	Primary: • Mean change from baseline in HbA1C at 24 week Secondary: • Mean change from baseline in 2h MTT at 24 week	• FSI Q2 12 • Est. Primary completion date Q2 14 • Est. Study completion date Q1 15 • Est. external presentation 2015
Type 2 Diabetes Mellitus	**Phase III** NCT01646320	N = 280	• **ARM 1:** Dapa 10 mg + Saxa 5 mg + Met IR • **ARM 2:** Placebo + Saxa 5 mg + Met IR Global study – 8 countries	Primary: • Mean change from baseline in HbA1C at 24 week Secondary: • Mean change from baseline in FPG at 24 week	• FSI Q3 12 • Est. Primary completion date Q3 14 • Est. Study completion date Q1 15 • Est. external presentation 2015

*studies performed by BMS

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 III DURATION-NEO 1 Partnered** NCT01652716	N = 375	• **ARM 1:** Exenatide BiD SC (autoinjector) • **ARM 2:** Exenatide weekly suspension SC (autoinjector) On a background of diet & exercise alone or with stable regimen of oral antidiabetes US only	• Change in HbA1c from baseline at 28 weeks	• FSI Q1 13 • Est. completion date Q3 14 • Est. external presentation Q3 14
Type 2 Diabetes	**Phase III DURATION-NEO 2 Partnered** NCT01652729	N = 360	• **ARM 1:** Sitagliptin • **ARM 2:** Exenatide weekly suspension SC (autoinjector) • **ARM 3:** Placebo On a background of diet & exercise alone or with stable regimen of oral antidiabetes US only	• Change in HbA1c from baseline at 28 weeks	• FSI Q1 13 • Est. completion date Q2 14 • Est. external presentation Q3 14
Type 2 Diabetes	**Phase IV EXSCEL Partnered** NCT01144338	N = 14000	• **ARM 1:** *Bydureon* once weekly 2mg SC • **ARM 2:** Placebo On a background of standard of care medication, different degree of CV risk Global study	• Time to first confirmed CV event in the primary composite CV endpoint (CV death, non-fatal MI, non-fatal stroke)	• FSI Q2 10 • Est completion date Q2 18 • 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 hyper-triglyceridaemia	**Phase III EVOLVE II** **NCT02009865**	N = 104	• **ARM 1:** Epanova 2g QD • **ARM 2:** Placebo (olive oil) Global study – 7 countries	• Change in serum triglycerides over 12 weeks	• FSI Q4 13 • LSI Q4 14 • Est completion date Q4 15
Patient with hypertri-glyceridaemia and high CVD risk	**Phase III STRENGTH** **NCT02104817**	13,000	• **ARM 1:** Epanova 4g QD + statin • **ARM 2:** Placebo (corn oil) + statin Global study – 18 countries	• Composite of MACE	• FSI planned to H2 14 • Est completion date Q2 19

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:** Metreleptin 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:** Metreleptin 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)

EGFR M+ NSCLC development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
EGFR M+ NSCLC who have progressed on 1st line IRESSA	**Phase III IMPRESS** **NCT01544179**	N = 250	• **ARM 1:** Gefitinib 250 mg QD + max 6 cycles of cisplatin and pemetrexed • **ARM 2:** Placebo + max 6 cycles of cisplatin and pemetrexed Global study – 11 countries	• Progression Free Survival • Overall Survival is a secondary endpoint	• FSI Q1 12 • LSI Q4 13 • Est completion date Q2 14 • Est. external presentation: Q3 14
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	• Safety • Optimal biologic dose for the combination • Secondary endpoints include tumour response, Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics	• 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 (1st-line)	**Phase III FALCON** **NCT01602380**	N ~450	• **ARM 1:** Faslodex 500 mg monthly IM + an additional dose on d14 (+ oral placebo) • **ARM 2:** Arimidex 1 mg (+ placebo injection) Global study – 21 countries	• Progression Free Survival (PFS) • Overall Survival is a secondary endpoint	• FSI Q4 12 • LSI Q4 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 (2nd-line)	**Phase III** **NCT01300351**	N = 221	• **ARM 1:** Faslodex 500 mg monthly IM + an additional dose on day 14 • **ARM 2:** Faslodex 250 mg monthly IM China study	• Progression Free Survival	• FSI Q1 11 • LSI Q4 13 • Est primary Completion Date Q1 14 • Est. external presentation Q4 14 San Antonio Breast Cancer Symposium

Caprelsa

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	• **ARM 1:** Vandetanib 300 mg oral dose QD • **ARM 2:** Placebo Global study – 12 countries	• Progression Free Survival	• 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	• **ARM 1:** Vandetanib 300mg oral dose QD Japanese patients	• Frequency and severity of adverse events • Secondary end point objective response rate	• 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	• **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 Global study – 19 countries	• 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	• FSI Q3 14 • LSI Q3 15 • Est. completion date Q4 16 • Est. external presentation beyond planning horizon

Zinforo

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	• **Arm 1:** Ceftaroline fosamil 600 mg q 8 hrs • **Arm 2:** Vancomycin plus aztreonam	• NI in Clinical Cure rate at the Test of Cure (TOC) visit in both the modified Intent-To-Treat (IIT) 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	• FSI Q2 12 • LSI Q2 14 • Est completion date Q2 14
Patients with Community-Acquired Pneumonia (CAP) in Asia	**Phase III CAP** NCT01371838	N = 692	• **Arm 1:** Ceftaroline fosamil 600 mg q 12 hrs • **Arm 2:** Ceftriaxone 2 g q 24 hrs	• 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	• FSI Q4 11 • LSI Q2 13 • Est completion date Q2 13 • Est external presentation Q2 14

FluMist Quadrivalent

Phase III development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Healthy children	**Phase III** **To be posted shortly**	N = 1008	• **ARM 1:** One or two doses of MEDI3250 • **ARM 2:** Placebo Nasal administration Japan only	• Efficacy • Safety and tolerability	• FSI Q3 14 • Est completion Q2 15
Healthy children	**Phase III** **To be posted shortly**	N =100	• **ARM 1:** One or two doses of MEDI3250 Nasal administration Japan only	• Safety and tolerability	• FSI Q3 14 • Est completion Q4 14

Gastrointestinal

Phase III development programme

	Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Nexium	**Refractory RE**	**Phase III Rose** NCT01669811	N = 280	• **ARM 1:** Nexium 20 mg BiD • **ARM 2:** Nexium 20 mg QD Japan-only study	• Healing of refractory RE	• FSI Q3 2012 • LSI Q1 2014 • Completion date Q2 2014 • Targeted as late breaking abstract at ACG Oct 2014 or DDW May 2015
Nexium	**Seriously ill patients (Stress Ulcer Prophylaxis, SUP)**	**Phase III** NCT02157376	N=300	• **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	• Proportion of patients with upper GI bleeding	• 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	• **ARM 1:** Entocort 9 mg QD • **ARM 2:** Mesalazine 1 g TD Japan-only study	• Remission defined by a CDAI score of ≤150	• FSI Q1 12 • LSI Q2 14 • Est completion Q4 14 • Est external presentation 16
Linaclotide	**IBS-C**	**Phase III** NCT01880424	N = 800	• **ARM 1:** Linaclotide 290µg QD • **ARM 2:** placebo Participating countries China, Australia, New Zealand	• 12-week abdominal pain/abdominal discomfort response • 12-week IBS degree of relief response	• FSI Q3 13 • LSI Q3 14 • Est completion date Q4 14 • Est external presentation 16

AstraZeneca

Late stage development programmes

2Q 2014 Results Update

AstraZeneca

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	• **ARM 1:** Roxadustat • **ARM 2:** Placebo Global study – 14 countries	• Haemoglobin response	• Sponsored by FibroGen • FSI Q4 12 • Est completion Q1 16
	Phase III ***Alps*** NCT01887600	N = 600	• **ARM 1:** Roxadustat • **ARM 2:** Placebo Global study – 14 countries	• Haemoglobin response	• Sponsored by Astellas • FSI Q2 13 • Est completion Q2 16
	Phase III ***Dolomites*** NCT02021318	N = 570	• **ARM 1:** Roxadustat • **ARM 2:** Darbepoetin alfa Global study – 8 countries	• Haemoglobin response	• Sponsored by Astellas • FSI Q1 14 • Est completion Q3 17
	Phase III ***Olympus*** NCT02174627	N = 5200 enrolled, 2600 randomized	• **ARM 1:** Roxadustat • **ARM 2:** Placebo Global study – 4 countries	• MACE	• Sponsored by AstraZeneca • FSI Q2 14 • Est completion Q1 17
Anaemia in CKD in Patients Receiving Dialysis	**Phase III** ***Rockies*** NCT02174731	N = 2850 enrolled, 1425 randomized	• **ARM 1:** Roxadustat • **ARM 2:** Epoetin alfa Global study – 5 countries	• MACE	• Sponsored by AstraZeneca • FSI Q2 14 • Est completion Q1 17
Anaemia in Newly Initiated Dialysis Patients	**Phase III** ***Himalayas*** NCT02052310	N = 750	• **ARM 1:** Roxadustat • **ARM 2:** Epoetin alfa Global study – 3 countries	• Haemoglobin response	• Sponsored by FibroGen • FSI Q4 13 • Est completion Q2 16

Olaparib (PARP inhibitor)

Solid tumours development programme

Patient Population	Phase Study	# of patients	Design	Primary Endpoint	Status
PSR BRCAm ovarian cancer	**Phase III SOLO-2** NCT01874353	N = 264	• **ARM 1:** olaparib tablets 300 mg BiD as maintenance therapy until progression • **ARM 2:** placebo tablets BiD Global study – 16 countries	• Progression Free Survival • Overall Survival is a secondary endpoint.	• FSI Q3 13 • LSI Q1 15 • Primary analysis planned Q3 15 • Primary presentation Q2 16
1st line maintenance BRCAm ovarian cancer	**Phase III SOLO-1** NCT01844986	N = 344	• **ARM 1:** olaparib tablets 300 mg BiD maintenance therapy for 2 years or until disease progression • **ARM 2:** placebo Global study – 15 countries	• Progression Free Survival • Overall Survival is a secondary endpoint.	• FSI Q3 13 • LSI Q1 15 • Primary analysis planned Q3 16 • Primary presentation Q2 17
2nd line gastric cancer (all patients with a co-primary sub population)	**Phase III GOLD** NCT01924533	N = 500	• **ARM 1:** paclitaxel + olaparib until progression • **ARM 2:** paclitaxel + placebo olaparib dose 100mg BiD throughout paclitaxel dose cycle & 300 mg BiD post cycle The study will be conducted in Korea, China, Taiwan and Japan	• Overall Survival	• FSI Q3 13 • LSI Q3 15 • Est completion date Q3 16 • Est external presentation Q3 17
BRCAm metastatic breast cancer	**Phase III OlympiAD** NCT02000622	N = 310	• **Arm 1:** Olaparib 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	• Progression Free Survival • Overall Survival is a secondary endpoint	• FSI Q2 14 • LSI Q4 15 • Est completion date Q2 16 • External Presentation Q2 17
Metastatic Castration Resistant Prostate CA	**Phase II** NCT01972217	N = 170	• **ARM 1:** Olaparib 200 or 300mg BiD + Abiraterone • **ARM 2:** Placebo + Abiraterone Global study	• Radiologic Progression Free Survival	• FSI Q2 14 • LSI Q3 2017 • Est completion date Q316

Olaparib (PARP inhibitor) continued...

Solid tumours development programme

Patient Population	Phase Study	# of patients	Design	Primary Endpoint	Status
BRCAm adjuvant breast cancer	**Phase III OlympiA** NCT02032823	N = 1320	• **Arm 1:** Olaparib 300 mg BiD 12 month duration • **Arm 2:** Placebo 12 month duration Global study partnership with BIG and NCI/NRG	• IDFS • Secondary Endpoint DFS and OS	• FSI Q2 14 • LSI Q1 18 • Est primary analysis Q1 20
Pancreas gBRCA	**Phase III POLO** NCT02184195	N = 145	• **Arm 1:** olaparib tablets 300 mg twice daily as maintenance therapy until progression. • **Arm 2:** placebo tablets BiD • Global Study approx 10 countries	• Primary Endpoint PFS • OS secondary endpoint	• FSI Q3 2014 • LSI: Q4 2015 • Results : Q1 2016 • Presentation: Q2 2016

Selumetinib (AZD6244, ARRY142886) (MEK-inhibitor)

Solid tumours development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
2nd Line KRAS M positive NSCLC	**Phase III SELECT-1** NCT01933932	N = 634	• **ARM 1:** Selumetinib 75mg BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle • **ARM 2:** Placebo BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle Global study – 26 countries	• Progression Free Survival • Overall Survival is a secondary endpoint.	• 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	• **ARM 1:** Selumetinib 75mg BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle • **ARM 2:** Selumetinib 75mg BiD + docetaxel 60 mg/m2 IV on day 1 of each 21 day cycle • **ARM 3**: Placebo BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle Global study – 7 countries	• Progression Free Survival • Overall Survival is a secondary endpoint.	• FSI Q4 12 • LSI Q4 14 • Est completion date Q3 15 • Est external presentation 2015
Metastatic Uveal Melanoma	**Phase III SUMIT** NCT01974752	N = 128	• **ARM 1:** Selumetinib 75 mg BiD + dacarbazine 1000 mg/m^2 day 1 of every 21 day cycle • **ARM 2:** Placebo BiD + dacarbazine 1000 mg/m^2 day 1 of every 21 day cycle 3:1 Randomisation Global study – 10 countries	• Progression Free Survival	• FSI Q2 14 • LSI Q1 15 • Est completion date Q2 15 • Est external presentation 2015
Differentiated Thyroid Cancer	**Phase III ASTRA** NCT01843062	N = 304	• **ARM 1:** Selumetinib 75mg BiD 5 weeks duration + RAI 100mCi[a] • **ARM 2:** Placebo BiD 5 weeks duration + RAI 100mCi[a] Global study – 8 countries [a] Single dose of 100mCi ^{131}I administered following 4 weeks of selumetinib (or placebo).	• Complete remission (CR) rate at 18 months post-RAI • Clinical remission rate at 18 m post RAI (per SoC)	• FSI Q3 13 • LSI Q4 14 • Est completion date Q216 • Estimated external presentation beyond planning horizon

AZD9291 (3rd Generation EGFR TKI)

NSCLC development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Advanced EGFR m+ NSCLC TKI failure + /- primary resistance mutation T790M	**Phase I/II AURA** NCT01802632	N ~ 500	• Dose escalation study • Ph II Extension cohort 80mg QD	• Safety and tolerability • ORR • PFS and OS secondary endpoints	• FSI Q1 13 • Est completion Q2 15 • Next external presentation Q3 14 (ESMO) • Est external presentation final data Q2 15 (ASCO)
Advanced EGFR m+ NSCLC TKI failure and primary resistance mutation T790M	**Phase II AURA2** NCT02094261	N = 175	• **ARM 1:** AZD9291 80 mg QD Global study – 8 countries	• ORR • PFS and OS secondary endpoints	• FSI Q2 14 • Est completion Q3 15 • Est external presentation: TBD
Advanced EGFR m+ NSCLC TKI failure and primary resistance mutation T790M	**Phase III AURA 3** NCT02151981	N= 610	• **ARM 1**: AZD9291 80mg QD • **ARM2:** pemetrexed 500mg/m2 + carboplatin AUC5 or pemetrexed 500mg/m2 + cisplatin 75mg/m2 (2:1 randomization)	• PFS • OS and QoL as secondary endpoints	• FSI Q3 14 • Est completion Q2 16 • Est external presentation: TBD
Advanced EGFRm+ NSCLC TKI failure	**Phase Ib TATTON** NCT02143466	N ~ 90	• AZD9291 in combination with MEDI4736 • AZD9291 in combination with AZD6094 • AZD9291 in combination with selumetinib	• Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity	• FSI Q3 14 • Est completion Q3 15 • Est external presentation: TBD

Anti-PD-L1 (MEDI4736)

Solid tumours development programme

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	• **ARM 1:** MEDI4736 IV Q2W (EFGR/ALK WT) • **ARM 2:** MEDI4736 IV Q2W (EFGR/ALK M+) Global study – 18 countries	• Objective Response Rate • Secondary endpoints include duration of response, progression free survival and overall survival	• FSI Q1 14 • LSI Q2 15 • Est completion date Q2 15 • Est external presentation: 2016
Unresectable Stage III NSCLC patients following platinum-based concurrent chemo-radiation therapy	**Phase III Pacific** **NCT02125461**	N = 702	• **ARM 1:** MEDI4736 IV Q2W • **ARM 2:** placebo Global study	• Progression Free Survival (PFS) • Overall Survival (OS)	• FSI Q2 14 • LSI Q2 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 = 484	• **ARM 1:** MEDI4736 IV Q2W (PD-L1+ patients) vs • **ARM 2:** Standard of Care • **ARM 3:** MEDI4736+tremelimumab IV Q4W (PD-L1 –ve patients) vs • **ARM 4:** Standard of Care	• Progression Free Survival (PFS) • Overall Survival (OS)	<u>Monotherapy arm</u> • Planned: FSI Q3 14 • LSI 4Q15 • Est completion date 1Q17 (PFS) <u>Combination therapy</u> • Planned: FSI Q3 14 • LSI 2Q15 • Est completion date 3Q16 (PFS) • Est external presentation beyond planning horizon

Anti-PD-L1 (MEDI4736) continued…

Solid tumours development programme

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 • **ARM 1:** MEDI4736Unmatched biomarker IVQ2W • **ARM 2:** AZD4547 (FGFR inhibitor) • **ARM 3:** CDK4/6 inhibitor • **ARM 4:** PI3K Inhibitor • **ARM 5:** HGFR Inhibitor	• Progression Free Survival (PFS) • Overall Survival (OS)	• Planned: FSI Q3 14 • LSI (Phase II Q1 15) • Est completion date Q4 16 • Estexternal presentation beyond planning horizon
Stage IIIB-IV NSCLC patients	**Phase I/II Sequencing Study** **NCT02179671**	N = 72	• **ARM 1:** Iressa initially then switch to MEDI4736 IVQ2W • **ARM 2:** AZD9291 then switch to MEDI4736 • **ARM 3:** Selumetinib + Docetaxel then switch to MEDI4736 • **ARM 4:** tremelimumab then switch to MEDI4736	• Complete Response Rate • ORR, Disease Control Rate	• Planned: FSI Q3 14 • LSI Q2 15 • Est completion date Q2 16 • Est external presentation: 2016
NSCLC, SCCHN HCC, pancreas, triple-negative BC, gastroesophageal, uveal melanoma, cutaneous melanoma	**Phase I** **NCT01693562**	N = 220	• **Dose Escalation:** 5 cohorts at Q2W and 1 cohort at Q3W • **Dose Expansion:** At least 8 tumor type cohorts at the Q2W MTD defined during dose escalation Global study – 5 countries	• Safety • Optimal biologic dose • Secondary endpoints include PK, immunogenicity and antitumor activity	• FSI Q3 12 • LSI Q4 14 • Est completion Q2 15 • Est external presentations Q2 14 of both dose escalation and dose expansion (ASCO) • Further potential update Q3 14 (ESMO)
Solid tumors (all comers)	**Phase I** **NCT01938612**	N = 24	• **Dose Escalation:** 3 cohorts at Q2W and 1 cohort at Q3W This study is being conducted in Japan	• Safety • Optimal biologic dose	• FSI Q3 13 • LSI Q4 14 • Est completion Q2 16

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	• **ARM 1:** Tremelimumab IV • **ARM 2:** Placebo	• Overall survival (OS)	• FSI Q2 13 • LSI Q2 15 • External presentation Q2 14 (ASCO)

Moxetumomab Pasudotox (anti-CD22)

Haematological malignancies development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Adults with relapsed refractory HCL	**Phase I** NCT00586924	N = 75	• 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	• Duration of response (CR and PR) • ORR, PFS, TTF • Safety and tolerability • Clinical activity of CAT-8015	• 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 Q3 14
Pediatrics with relapsed or refractory pALL or lymphoblastic lymphoma of B-cell origin	**Phase II** To be posted	N = 76	• Multicenter, Single-arm, Open label study	• Evaluate efficacy by MRD negative CRc rate, ORR (CR, CRi, PR), DCOR, DOR, PFS and OS • Safety and tolerability • Evaluate PK	• FSI Q3 14 • LSI Q2 16 • Est Completion Q4 17

Anti-IL-5Rα (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 ± chronic OCS **Age 12 – 75yrs**	**Phase III CALIMA** NCT01914757	N = 102 6 HD + up to 250 MD	• **ARM 1:** 30 mg Q8w SC • **ARM 2:** 30 mg Q4w SC • **ARM 3:** Placebo SC 56-week study Global study – 11 countries	• Annual Asthma Exacerbation Rate • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalization visits, PK, and IM	• FSI Q4 13 • Est completion date Q1 16
Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA ± chronic OCS **Age 12 – 75 yrs**	**Phase III SIROCCO** NCT01928771	N = 1134	• **ARM 1:** 30 mg Q8w SC • **ARM 2:** 30 mg Q4w SC • **ARM 3:** Placebo SC 48-week study Global study – 17 countries	• Annual Asthma Exacerbation Rate • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalization visits, PK, and IM	• FSI Q4 13 • Est completion date Q1 16
Severe asthma, inadequately controlled on high dose inhaled corticosteroid plus long-acting β2 agonist and chronic oral corticosteroid therapy **Age 18 – 75 yrs**	**Phase III ZONDA** NCT02075255	N = 120	• **ARM 1:** 30 mg Q8w SC • **ARM 2:** 30 mg Q4w SC • **ARM 3:** Placebo SC 46-week study Global study – 7 countries	• Reduction of Oral Corticosteroid dose	• FSI Q3 14 • Est completion date Q1 16

Anti-IL-5Rα (benralizumab)

COPD development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Subjects with moderate-to-severe COPD who exhibit eosinophilia (≥ 3.0% sputum eosinophilia)	**Phase IIa** NCT01227278	N = 101	• **ARM 1:** 100mg Q8w SC • **ARM 2:** Placebo SC	• Rate of Exacerbations	• Completed Q3 13 • Est external presentation Q2 14 (ATS)
Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD) with Exacerbation History	**Phase III TERRANOVA** NCT02155660	N = 2324	• **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 – 17 countries	• Rate of COPD Exacerbation	• 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	• **ARM 1:** 30 mg Q4w SC • **ARM 2:** 100 mg Q8w SC • **ARM 3:** Placebo SC 48-week study Global study – 15 countries	• Rate of COPD Exacerbation	• FSI Q3 14 • Est completion date Q4 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	• **ARM 1:** GFF MDI (PT003) 14.4/9.6 µg • **ARM 2:** GP MDI (PT001) 14.4 µg • **ARM 3:** FF MDI (PT005) 9.6 µg • **ARM 4:** Open-label tiotropium bromide inhalation powder • **ARM 5:** Placebo MDI 24 week study US, Australia, New Zealand	• Change from baseline in morning pre-dose trough FEV_1	• FSI Q2 13 • LSI Sept 14 • Results Q2 15*
Moderate to Very Severe COPD	**Phase III** **PINNACLE 2** NCT01854658	N = 1614	• **ARM 1:** GFF MDI (PT003) 14.4/9.6 µg • **ARM 2:** GP MDI (PT001) 14.4 µg • **ARM 3:** FF MDI (PT005) 9.6 µg • **ARM 4:** Placebo MDI 24 week study US, Australia, New Zealand	• Change from baseline in morning pre-dose trough FEV_1	• FSI Q3 13 • LSI Sept 14 • Results Q2 15*
Moderate to Very Severe COPD	**Phase III** **PINNACLE 3** NCT01970878	N = 850	• **ARM 1:** GFF MDI (PT003) 14.4/9.6 µg • **ARM 2:** GP MDI (PT001) 14.4 µg • **ARM 3:** FF MDI (PT005) 9.6 µg • **ARM 4:** Open-label tiotropium bromide inhalation powder 28 week extension US, Australia, New Zealand	• Overall safety, tolerability and efficacy	• FSI Q4 13 • LSI Sept14 • Results Q2 15

*Results for Phase III efficacy studies to remain blinded until completion of PINNACLE 3 safety extension. Overall summary of Phase III data available in Jan 2015

Anti-IL-17RA (brodalumab)

Inflammatory diseases development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Moderate to severe plaque psoriasis	**Phase III AMAGINE-1** NCT01708590	N = 661	• **ARM 1:** 210 mg brodalumab SC • **ARM 2:** 140 mg brodalumab SC • **ARM 3:** placebo SC	• PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12	• Primary data Q2 14
Moderate to severe plaque psoriasis	**Phase III AMAGINE-2** NCT01708603	N = 1800	• **ARM 1:** 210 mg brodalumab SC • **ARM 2:** 140 mg brodalumab SC • **ARM 3:** 45 or 90 mg ustekinumab SC • **ARM 4:** placeboSC	• PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12	• FSI Q3 12 • Est completion date H2 14 • Est external presentation Q1 15
Moderate to severe plaque psoriasis	**Phase III AMAGINE-3** NCT01708629	N = 1881	• **ARM 1:** 210 mg brodalumab SC • **ARM 2:** 140 mg brodalumab SC • **ARM 3:** 45 or 90 mg ustekinumab SC • **ARM 4:** placeboSC	• PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12	• FSI Q3 12 • Est completion date H2 14 • Est external presentation Q1 15
Moderate to severe Psoriatic Arthritis	**Phase II** NCT01516957	N = 156	• **ARM 1:** 280 mg brodalumab SC • **ARM 2:** 210 mg brodalumab SC • **ARM 3:** 140 mg brodalumab SC • **ARM 4:** placebo SC	• ACR20 response at wk 12	• Primary data Q4 12 • OLE ongoing, FSI Q1 14 • External presentation 12w data EULAR 2013, 24w data ACR 2013
Moderate to severe inadequately controlled high reversibility asthma	**Phase II** NCT01902290	N = 566	• **ARM 1:** 210 mg brodalumab SC • **ARM 2:** placebo SC	• Change in ACQ at wk 24	• FSI Q2 13 • Est completion date Q1 15
Adult subjects with Psoriatic Arthritis	**Phase III AMVISION-1** NCT02029495	N = 630	• **ARM 1:** 210mg brodalumab SC • **ARM 2:** 140 mg brodalumab SC • **ARM 3:** placebo SC	Primary: • ACR20 response at wk 16 Secondary • Radiographic assessment of joints • PASI 75, HAQ-DI and PSI	• FSI March 2014 • Recruitment Ongoing • Est primary completion Q1 16
Adult subjects with Psoriatic Arthritis	**Phase III AMVISION-2** NCT02024646	N = 495	• **ARM 1:** 210mg brodalumab SC • **ARM 2**: 140 mg brodalumab SC • **ARM 3**: placebo SC	• ACR20 response at wk 16	• FSI March 2014 • Recruitment Ongoing • Est primary completion Q1 16

Lesinurad (URAT1)

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	• **Arm 1:** Placebo • **Arm 2:** lesinurad 200 mg QD • **Arm 3:** lesinurad 400 mg QD All arms: SOC allopurinol QD	• Proportion of subjects with an sUA level that is < 6.0 mg/dL by Month 6	• FSI Q1 12 • LSI Q3 13 • Est completion date Q3 14 • Est external present Q4 14 (ACR)
Gout with Inadequate Hypouricemic Response to Allopurinol	**Phase III CLEAR 2** NCT01493531	N = 600	• **Arm 1:** Placebo • **Arm 2:** lesinurad 200 mg QD • **Arm 3:** lesinurad 400 mg QD All arms: SOC allopurinol QD	• Proportion of subjects with an sUA level that is < 6.0 mg/dL by Month 6	• FSI Q4 11 • LSI Q2 13 • Est completion date Q3 14 • Est external present Q4 14 (ACR)
Tophaceous Gout	**Phase III CRYSTAL** NCT01510769	N = 315	• **Arm 1:** Placebo • **Arm 2:** lesinurad 200 mg QD • **Arm 3:** lesinurad 400 mg QD All arms: febuxostat 80 mg QD	• Proportion of subjects with an sUA level that is < 5.0 mg/dL by Month 6	• FSI Q1 12 • LSI Q2 13 • Est completion date Q3 14 • Est external present Q4 14 (ACR)
Gout with Intolerance or Contraindication to a Xanthine Oxidase Inhibitor	**Phase III LIGHT** NCT01508702	N = 200	• **Arm 1:** Placebo • **Arm 2:** lesinurad 400 mg QD	• Proportion of subjects with an sUA level that is < 6.0 mg/dL at Month 6	• FSI Q1 12 • LSI Q2 13 • Study complete, press release issued • Est external present Q4 14 (ACR)
Gout previously enrolled LIGHT study	**Phase III LIGHT Ext** NCT01650246	N = 143	All arms: open-label lesinurad 400 mg QD	• Assess the long-term efficacy and safety of lesinurad monotherapy.	• FSI Q4 12 • LSI 1Q 14 • Study complete • Est external present Q4 14 (ACR)
Gout previously enrolled in studies CLEAR 1 & 2	**Phase III CLEAR Ext** NCT01808131	N ≤ 200	• **Arm 1:** lesinurad 200 mg QD • **Arm 2:** lesinurad 400 mg QD All arms: SOC allopurinol QD	• Assess the long-term efficacy and safety of lesinurad in combination with allopurinol.	• FSI Q1 13 • Recruitment ongoing
Gout previously enrolled in CRYSTAL study	**Phase III CRYSTAL Ext** NCT01808144	N ≤ 315	• **Arm 1:** lesinurad 200 mg QD • **Arm 2:** lesinurad 400 mg QD All arms: febuxostat 80 mg QD	• Assess the long-term efficacy and safety of lesinurad in combination with febuxostat.	• FSI Q1 13 • Recruitment 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	• **ARM 1:** CAZ-AVI 2000/500mg plus Metronidazole IV • **ARM 2:** Meropenem IV Global study – 20 countries	• Co primary of: (i) clinical response at TOC (MITT) (ii) clinical response at TOC (i.e. clinically evaluable)	• FSI Q1 12 • LSI Q2 14 • Est completion date Q3 14 • Est external presentation Q2 15
Hospitalised patients with complicated intra-abdominal infections	**Phase III RECLAIM-2** NCT01500239	N = 576	• **ARM 1:** CAZ-AVI 2000/500mg plus Metronidazole IV • **ARM 2:** Meropenem IV Global study – 21 countries	• Co primary of: (i) clinical response at TOC (MITT) (ii) clinical response at TOC (i.e. clinically evaluable)	• FSI Q2 12 • LSI Q2 14 • Est completion date Q3 14 • Est external presentation Q2 15
Hospitalised Adults With complicated urinary tract Infections	**Phase III RECAPTURE-1** NCT01595438	N = 520	• **ARM 1:** CAZ-AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • **ARM 2:** Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim Global study – 26 countries	• Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT)	• FSI Q4 12 • LSI Q3 14 • Est completion date Q4 14 • Est external presentation Q3 15
Hospitalised patients with complicated urinary tract infections	**Phase III RECAPTURE-2** NCT01599806	N = 511	• **ARM 1:** CAZ-AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • **ARM 2:** Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim Global study – 25 countries	• Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT)	• FSI Q4 12 • LSI Q3 14 • Est completion date Q4 14 • 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 = 400	• **ARM 1:** CAZ-AVI 2000/500mg plus Metronidazole IV • **ARM 2:** Best available therapy Global study – 30 countries	• Patients with clinical cure at the Test of Cure visit in the microbiological intent to treat analysis set	• FSI Q1 13 • LSI Q1 15 • Est completion date Q2 15 • Est external presentation 2015
Hospitalised patients with complicated intra-abdominal infections	**Phase III RECLAIM-3** NCT01726023	N = 404	• **ARM 1:** CAZ-AVI 2000/500mg plus Metronidazole IV • **ARM 2:** Meropenem IV Asia-focused study – 3 countries (China, Vietnam & Korea)	• Clinical Cure at the TOC visit in the MITT analysis set	• 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	• **ARM 1:** CAZ-AVI 2000/500mg IV • **ARM 2:** Meropenem IV Global study – 24 countries	• Proportion of patients with clinical cure at the TOC visit in the cMITT and CE analysis sets (co-primary analyses).	• FSI Q2 13 • LSI Q2 16 • Est completion date Q3 16 • Est external presentation beyond planning horizon

AstraZeneca

Early development programmes

2Q 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	• **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 Conducted in the US, UK, Slovakia, Poland	• **Change in serum phosphate levels** • Dose response relationship of AZD1722 on serum phosphate levels • Number of patients reaching serum phosphate goal levels vs placebo	• FSI Q1 14 • LSI Q3 14 • Completion date Q4 14 • Est external presentation Q4 15
Patients with ESRD on HD	**Phase IIa** NCT01764854	N = 86	• **ARM 1:** AZD1722, starting dose 45 mg BiD, down titration based on tolerability • **ARM 2:** Placebo Conducted in the US	• **Reduction in mean weekly interdialytic weight gain (IDWG)** • Effect of AZD1722 on IDWG after weekly intervals of treatment	• FSI Q1 13 • LSI Q413 • Completion date Q4 13 • Est external presentation Q4 15
Patients with Chronic Kidney Disease (CKD), Type 2 Diabetes and Albuminuria	**Phase IIa** NCT01847092	N = 140	• **ARM 1:** AZD1722, starting dose 15 mg BiD, dose escalation based on tolerability (max 60 mg BiD) • **ARM 2:** Placebo Conducted in the US, Germany	• **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.	• FSI Q2 13 • LSI Q4 14 • Completion date Q4 14 • Est external presentation Q4 15
Patients with constipation predominant Irritable Bowel Syndrome (IBS-C)	**Phase IIb** NCT01923428	N = 360	• **ARM 1:** AZD1722, 5 mg BiD • **ARM 2:** AZD1722, 20 mg BiD • **ARM 3:** AZD1722, 50 mg BiD • **ARM 4:** Placebo Conducted in the US	• **Percent Complete Spontaneous Bowel Movement (CSBM) responders** • Percent abdominal pain responders • Percent overall responder for both • CSBM and abdominal pain	• FSI Q3 13 • LSI Q2 14 • Completion date Q4 14 • Est external presentation Q4 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	• **ARM 1:** AZD4901 20 mg QD • **ARM 2:** AZD4901 20 mg BiD • **ARM 3:** AZD4901 40 mg BiD • **ARM 4:** placebo 28 day dosing period Study sites in US, UK, Germany	• Change from baseline at day 7 in Luteinizing Hormone AUC(0-8) Secondary endpoints: • Change from baseline in free and total testosterone at day 7 & day 28	• FSI Q2 13 • LSI Q2 14 • Est completion Q3 14 • External presentation Q2 15 (ENDO or ESHRE)

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)	• Single Ascending Dose study – single-center, single-blind, randomized and placebo-controlled. • 7 planned cohorts/dose levels	• Safety and tolerability	• 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	• **ARM 1:** carbo/paclitaxel + AZD1775 225mg • **ARM 2:** carbo/paclitaxel + placebo Global study 9 countries	• Progression Free Survival • Overall Survival is a secondary endpoint.	• FSI Q4 11 • LSI Q3 14 • Est completion Q1 15 • Est external presentation Q2 16 (ASCO)
Previously Untreated Stage IV Non-Squamous NSCLC with TP53 mutations	**Phase II** NCT02087241	N = 130	• **ARM 1:** carboplatin + pemetrexed + AZD1775 225 mg BiD • **ARM 2:** carboplatin + pemetrexed + placebo 6 patients safety lead in Conducted in US	• Progression Free Survival • Overall Survival is a secondary endpoint.	• FSI Q1 14 • LSI Q2 15 • Est completion Q4 15 • Est external presentation Q2 17 (ASCO)
Previously Treated NSCLC with TP53 mutations	**Phase II** NCT02087176	N = 135	• **ARM 1:** docetaxel + AZD1775 225 mg BiD • **ARM 2:** docetaxel+ placebo 20-25 patient run in for safety and efficacy Conducted in US	• Progression Free Survival • Overall Survival is a secondary endpoint.	• FSI Q1 14 • LSI Q2 15 • Est completion Q4 15 • 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	• **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) Conducted in Japan	• **Part A:** MTD and Recommended dose for Parts B and C • **Part B:** Safety and tolerability and preliminary anti-tumour activity	**Recruited** Q1 13 • 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	• **Part A:** AZD4547 in ascending multiple doses in combination with 25mg exemestane
			• **Part B:**
			  • **ARM 1:** AZD4547 (dose from part A) + fulvestrant
			  • **ARM 2:** placebo + fulvestrant
			
			Patients with FGFR1 polysomy (30 patients) or FGFR1 amplification (60 patients)
				• **Part A:** MTD of AZD4547 in combination with 25mg exemestane in three schedules of AZD4547
				• **Part B Interim analysis:** Tumour size analysis on 30 FGFR amplified patients
				• **Part B Final analysis:** Progression Free Survival
					Recruitment closed Q2 14
					
					• Est external presentation beyond planning horizon

Advanced gastro-oesophageal cancer	**Phase II SHINE** **NCT01457846**	N = 71	• **Stratum A** (FGFR2 polysomy): AZD4547 vs paclitaxel randomised 1:1 (30 to 80 patients) • **Stratum B** (FGFR 2 low gene amplification: AZD4547 vs paclitaxel randomised 3:2 (25 to 80 patients) • **Stratum C** (FGFR2 high gene amplification: AZD4547 vs paclitaxel randomised 3:2 (25 to 80 patients)	• Progression Free Survival • Key Secondary: Overall survival/Tumour size	**Recruitment closed** after an interim analysis Q2 13 • Est external presentation Q4 14
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 • **ARM 1:** MEDI4736Unmatched biomarker IVQ2W • **ARM 2:** AZD4547 (FGFR inhibitor) • **ARM 3:** CDK4/6 inhibitor • **ARM 4:** PI3K Inhibitor • **ARM 5:** HGFR Inhibitor	• Progression Free Survival (PFS) • Overall Survival (OS)	• Planned: FSI Q3 14 • LSI (Phase II Q1 15) • Est completion date Q4 16 • Estexternal 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	• **Dose escalation study** Conducted in Australia	• Safety and tolerability	• FSI Q1 12 • LSI Q4 14 • Est completion Q4 14 • Est external presentation Q2 15 (AACR & ASCO)
Advanced Cancer (All comers)	**Phase I** NCT01985555	N =70	• **Dose escalation study** Conducted in China	• Safety and tolerability	• FSI Q2 13 • LSI Q3 15 • Est completion Q4 14
Papillary Renal Cell Cancer	**Phase II** NCT02127710	N =75	• **Single arm study:** AZD6094 600mg QD Conducted in UK, US	• Overall Response Rate	• FSI Q2 14 • LSI Q3 15 • Est completion Q4 14

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*** **Not yet posted**	N = 300	• **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 The study will be conducted in Europe	• Progression Free Survival • Overall Survival is a secondary endpoint	• FSI Q2 14 • LSI Q4 15 • Est completion Q2 17 • Est external presentation Q4 17
Advanced Solid Malignancies	**Phase I** **NCT01026402**	N = ~163	• SAD and MAD with dose expansion. Continuous and intermittent dosing. Sites in UK	• Safety and tolerability of AZD2014	• FSI Q4 09 • LSI Q2 14 • Est completion Q3 14 • External presentation Q2 12 (ASCO)
ER+ Advanced Metastatic Breast Cancer	**Phase I** **NCT01597388**	N = ~70	• SAD and MAD. Continuous and intermittent dosing schedules in combination with fulvestrant Sites in US	• Safety and tolerability of AZD2014 in combination with fulvestrant • Determination of steady state PK profile of AZD2014 in combination with fulvestrant	• FSI Q2 12 • LSI Q4 14 • Est completion Q4 14 • Est external presentation Q4 14

*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	Monotherapy AZD5363 480mg BD 4 days on 3 days off • **Part C arm 1:** Breast with PIK3CA mutation • **Part C arm 2:** Gynaecological with PIK3CA mutation • **Part D arm 1:** Breast with AKT-1 mutation • **Part D arm 2:** Gynaecological with AKT-1 mutation • **Part D arm 3:** other tumours with AKT-1 mutation Possible expansion up to 120 patients per arm	• Safety and tolerability • Response Rate (ORR)	• FSI Q3 13 • Est completion Q3 15
ER+ breast cancer receiving 1st treatment with paclitaxel in the advanced setting	**Phase IIb** NCT01625286	N =100	• **ARM 1:** AZD5363 + paclitaxel • **ARM 2:** Paclitaxel alone Two strata: PIK3CA mutation positive vs Mutation not detected	• Progression Free survival (PFS) • Response rate (ORR) & overall survival are secondary endpoints	• Est completion Q4 16 • Est external presentation of Part A dose escalation Q4 14 (SABCS)
All-comers solid tumours	**Phase I** NCT01895946	N = min 12-24	• 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	• PK	• FSI Q1 14 • Est completion Q4 14

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 = 48	• **Part A:** AZD8186 monotherapy in ascending intermittent doses • **Part B:** AZD8186 monotherapy at recommended dose from Part A in PTEN deficient patients with advanced cancer Study conducted in Canada, US & UK	• **Part A:** PK, MTD and Recommended dose for Part B • **Part B:** Safety and tolerability and preliminary assessment of antitumor activity (POM)	• FSI Q3 13 • Est completion Q2 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	**Part A: Dose escalation** • AZD5312 in ascending multiple doses given iv (c. 30 patients) **Part B: Dose expansion** • AZD5312 at recommended dose from Part A, given iv • **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).	• **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	• FSI Q2 14 • Est completion Q2 16 • Est external presentation beyond planning horizon

Oncology

Haematological malignancies development programme

	Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
STAT3 (AZD9150)	**HCC**	**Phase I** NCT01839604	N = 80	• Dose-escalation and dose-expansion study • IV Study conducted in Japan, Korea, Taiwan and Hong Kong	• Safety and tolerability . • Recommended phase II dose and schedule	• FSI Q2 13 • Est completion Q1 15 • Est external presentation Q4 14
	DLBLC	**Phase I/II*** Partnered ISIS NCT01563302	N = 80	• Dose-escalation and dose-expansion study • IV Study conducted in US	• Safety and tolerability . • Recommended phase II dose and schedule	• FSI Q1 12 • Est completion Q2 15 • Est external presentation Q4 14
PIM (AZD1208)	**AML relapsed/ refractory**	**Phase I** NCT01489722	N = 74	• **SAD** North America – 4 sites	• Safety and tolerability • Dose finding/MTD • PK	• FSI Q2 12 • LSI Q2 14 • Estimated completion Q4 14* • Estimated external presentation Q4 14 (ASH)
	Solids and Lymphoma	**Phase I** NCT01588548	N = 40	• **SAD** Europe and Asia – 2 sites	• Safety and tolerability • Dose finding/MTD • PK	• FSI Q3 12 • LSI Q2 14 • Estimated completion Q4 14* • Estimated external presentation Q2 15
ATR (AZD6738)	**2nd Line B-cell lymphomas**	**Phase I** NCT01955668	N = 56	• **Dose Escalation (Part A):** AZD6738 20 mg BD starting dose; All comers B-cell lymphomas • **Dose Expansion (Part B):** AZD6738 MTD; 11q del or ATM deficient CLL US study	• Part A: Safety and tolerability, MTD • Part B: Safety, tolerability, PK and biological activity	• Study completed

* clinicaltrials.gov being updated

LABA/LAMA/ICS (PT010)

COPD development programme

Patient Population	Phase Study	# of patients	Design (B= Budesonide, G = Glycopyrronium, F = Formoterol fumarate)	Endpoint(s)	Status
Healthy volunteers	**Phase I** NCT01980615	N = 84	• **ARM 1:** BGF MDI 320/14.4/9.6 µg • **ARM 2:** BGF MDI 160/14.4/9.6 µg • **ARM 3:** BGF MDI 80/14.4/9.6 µg • **ARM 4:** GF MDI 14.4/9.6 µg • **ARM 5:** Symbicort MDI 320/9 µg • **ARM 6:** Symbicort MDI 160/9 µg Randomized, double-blind within device, four-period, six- treatment, cross-over Single centre Phase 1 unit	• Overall safety • PK parameters AUC0-12 and Cmax	• FSI Q4 13 • LSI Q4 13 • Completed • Est external presentation Q3 14 (ERS)

MABA (AZD2115)

COPD clinical development programme

Patient Population	Phase Study	# of Patients	Design	Endpoint(s)	Status
Healthy subjects	**Phase I** NCT01283984	N = 72	• **ARM 1:** SAD AZD2115 as nebulised solution • **ARM 2:** Placebo	• Safety and tolerability following inhaled administration with single ascending dose	• FSI Q1 11 • Est external presentation Q3 14
Healthy subjects	**Phase I** NCT01445782	N = 36	• **ARM 1:** SAD and MAD AZD2115 as nebulised solution • **ARM 2:** Placebo Conducted in UK	• Safety and tolerability following administration of multiple ascending inhaled doses	• FSI Q4 11 • Est external presentation Q3 14
COPD patients	**Phase IIa MISTRAL** NCT01498081	N = 39	• **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 Conducted in Sweden and Poland	• Peak and trough FEV1	• FSI Q1 12 • LSI Q2 13 • Est external presentation 2016
COPD patients	**Phase IIa** NCT02109406	N = 30	• **ARM 1:** AZD2115 Dose 1 BiD (pMDI) • **ARM 2:** AZD2115 Dose 2 BiD (pMDI) • **ARM 3:** placebo Multiple dose, 3 way cross over Conducted in US.	• FEV1 AUC(0-12) relative to baseline following chronic dosing on Day 15	• FSI (planned) Q2 14 • LSI Q2 14 • 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** • Five different dose levels investigated vs placebo • Inhaled (nebulised) administration Study conducted in the UK	• Safety and tolerability following inhaled administration with single ascending dose	• FSI: Q1 2013 • Completed • Estimated publication: 2015
Healthy subjects and COPD patients	**Phase I** NCT01817855	N = 44	**MAD** • Different dose levels investigated vs placebo in healthy volunteers and patients with COPD • Inhaled (nebulised) administration Study conducted in the UK	• Safety and tolerability in healthy subjects and patients with COPD following administration of multiple ascending inhaled doses	• FSI: Q3 13 • LSI: Q3 14 • Estimated completion: Q3 14 • Estimated publication: 2015
Healthy subjects	**Phase Ib LPS** NCT01937338	N = 60	• 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 Study conducted in the UK	• Effect on neutrophils in induced sputum after oral inhalation of LPS, compared to placebo	• FSI: Q4 13 • Completed • Estimated publication: 2015

TLR7 agonist (AZD8848)

Phase I clinical development programme

Patient Population	Phase Study	# of Patients	Design	Endpoint(s)	Status
Healthy subjects	**Phase I** NCT01560234	N = 4 active + 2 placebo per cohort	**SAD**	• Safety and tolerability of ascending doses of AZD8848 in healthy subjects • Secondary endpoints include PoM marker CXCL10	• Est completion Q3 14
Healthy subjects	**Phase I** NCT01818869	N = 6 active + 2 placebo per cohort	**MAD** • 2-3 cohorts investigated	• Safety and tolerability of ascending doses of AZD8848 in healthy subjects • Secondary endpoints include PoM marker CXCL10	• FSI Q1 14 • Est completion Q3 14

URAT1 (RDEA3170)

Gout development programme

Patient Population	Phase Study	# of patients	Design	Primary endpoint	Status
Subjects with Gout	**Phase II** NCT01927198	N = 160	• **Arm A:** Placebo • **Arm B:** RDEA3170 5 mg QD • **Arm C:** RDEA3170 10 mg QD • **Arm D:** RDEA3170 12.5 mg QD	• Efficacy and Safety at Week 24	• FSI Q3 13 • LSI Q4 13 • Estimated completion Q3 14
Japanese Patients with Gout or Asymptomatic Hyperuricemia	**Phase II** NCT02078219	N = 200	• **Arm A**: Placebo • **Arm B**: RDEA3170 5 mg QD • **Arm C**: RDEA3170 10 mg QD • **Arm D**: RDEA3170 12.5 mg QD • **Arm E**: Open-label Allo 100mg BiD	• To compare the efficacy of RDEA3170 monotherapy at Week 16 with placebo and Allopurinol.	• FSI: Q1 14 • LSI: Q3 14 • Estimated completion: Q1 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	• 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 Single centre in UK	• Safety/tolerability • Pharmacokinetics (secondary)	• FSI Q4 12 • LSI Q1 15 • Est completion date Q2 15 • Est presentation Q3 15 (ICAAC)
GyrAR (AZD0914)	**Healthy Volunteers**	**Phase I** NCT01929629	N = 70	• **Arm 1:** SAD • **Arm 2** Single doses food effect. Subjects to receive 2 single oral doses, one fed and one fasted • Single center in US	• Safety and tolerability Secondary • Pharmacokinetics • Effect of food on PK	• FSI Q3 13 • Study completed Q1 14 • Estimated presentation Q3 14 (ICAAC)
Rib50s (AZD5847)	**Extended Early Bactericidal Effect (EBA)***	**Phase IIa** NCT01516203	N = 75	• **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) Study conducted in Cape Town, South Africa	• Rate of change in sputum colony forming unit (CFU) counts during 14 days of study drug administration (EBA 0-14)	• LSI Q4 13 • Est completion date Q4 13 • Est. external presentation Q4 14

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

BACE (AZD3293)

Alzheimer's Disease development programme

Patient Population	Phase Study	# of Patients	Design	Endpoint(s)	Status
Healthy Volunteers	**Phase I SAD Study** NCT01739647	N =72	• **Active ARMS:** AZD3293 single doses, ascending doses ranging from 1mg to a maximum of 1000mg • **Comparator ARM:** placebo 1 site in US	• AEs, labs, vital signs, ECGs • PK • PD (Aβ 40 and 42 plasma)	• Study completed. • Poster presentation Clinical Trial in Alzheimer's Disease Conference November 2013. • Full data presented Springfield Alzheimer's Conference March 2014

Healthy volunteers and Alzheimer's Disease Patients	**Phase I MAD Study**
	NCT01795339
		N = 56	• **Active ARMS:**
			  • **(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
			
			1 site in US
				• AEs, labs, vital signs, ECGs
				• PK
				• PD (Aβ40 and 42 plasma and CSF)
					• Study completed.
					• Data from part 1 presented in Clinical Trial in Alzheimer's Disease Conference November 2013.
					• 2 more presentations of data in March and July 2014
					• AD patient data to be presented at Clinical Trial in Alzheimer's Disease Conference November 2014

Healthy Volunteers	**Phase I JSMAD Study** NCT02005211	N = 40	• **Active ARMS:** Ascending AZD3293 SAD (15, 50, 150 mg planned) and MAD (15, 50 mg doses planned) • **Comparator ARM:** placebo 1 site in Japan	• AEs, labs, vital signs, ECGs • PK • PD (Aβ 40 and 42 plasma)	• Study in reporting phase • FSI Q4 13 • LSI Q3 14

MPO (AZD3241)

Parkinson's Disease development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Healthy Subjects	**Phase I** NCT00729443	N = 46	• **Active ARMS:** SAD • **Comparator ARM:** placebo 1 site in Sweden	• AEs, labs, vital signs, ECGs • PK	• Study completed
Healthy Subjects	**Phase I** NCT01457807	N = 18	• **Active ARMS:** MAD • **Comparator ARM:** placebo 1 site in UK	• AEs, labs, vital signs, ECGs • PK	• Study completed
Healthy Subjects	**Phase I** NCT00914303	N = 59	• **Active ARMS:** MAD • **Comparator ARM:** placebo 1 site in Sweden	• AEs, labs, vital signs, ECGs • PK	• Study completed
Parkinson's Disease Patients	**Phase II** NCT01527695	N = 24	• **ARM 1:** AZD3241 600 mg BID for 8 weeks • **ARM 2:** Placebo Randomization 3:1 active to placebo. 3 sites in Sweden and Finland	• Microglia activation represented by [11C]PBR28 binding Secondary endpoints: • PD symptoms measured by UPDRS • Plasma MPO activity	• Study completed • Poster presented at Movement Disorders Society meeting June 2014
Parkinson's Disease Patients	**Phase II** NCT01603069	N = 51	• **ARM 1:** AZD3241 300 mg BID for 12 weeks • **ARM 2:** AZD3241 600 mg BID for 12 weeks • **ARM 3:** Placebo Randomization 1:1:1 across arms 13 sites in US	• AEs, labs, vital signs, ECGs Secondary endpoints: • PD symptoms measured by UPDRS • Plasma MPO activity	• 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	• **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
			  • **ARM 1:** AZD5213 low dose
			  • **ARM 2:** AZD5213 high dose
			  • **ARM 3:** Placebo
			
			US only study, 9 sites
				• Improvement in Total Tic Severity Score (TTS) on the Yale Global Tic Severity Scale (YGTSS) at the last day of receiving treatment.	• FSI Q4 13
					• LSI Q2 14
					• Est completion Q4 14
					• Est external presentation 2015

Painful Diabetic Neuropathy	**Phase IIa**
	NCT01928381
		N = 32	• **Part 1:** Training to improve reliability to assess pain.
			• **Part 2:** Randomized, double-blind, three-period, three-treatment, cross-over
			  • **ARM 1:** AZD5213 + Pregabalin
			  • **ARM 2:** Pregabalin
			  • **ARM 3:** Placebo
			
			US only study, 4 sites
				• Significant change on average severity of pain (BPI-DPN).	• FSI Q4 13
					• LSI Q2 14
					• Est completion Q2 14
					• 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	• **SAD/MAD:** Ascending dose cohorts of n=8 (6 active drug, 2 placebo); IV administration • 8 dose cohorts planned (5 SAD, 3 MAD)	• Safety and tolerability Additional endpoints: • Pharmacokinetics • Pharmacodynamic biomarker (qEEG)	• FSI Q3 13 • LSI Q1 14 • Study completed • Est. external presentation 2015

MedImmune

Early development programmes

2Q 2014 Results Update

AstraZeneca

Cardiovascular biologics early development

Phase I clinical development programme

	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	• Safety • Changes in total HDL • Change in Cholestryl 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	• FSI Q4 13 • LSI Q3 14 • Est completion Q4 14

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	• **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 Open label study	• ORR, including Complete Response (CR) or Partial Response (PR)	• FSI Q1 12 • Est completion Q4 14 • Est external presentation Q2 15
Adults with relapsed or refractory B-cell diffuse large B-cell lymphoma (DLBCL)	**Phase II** NCT01453205	N = 170	• **ARM 1:** MEDI-551 dose level 1 and ICE/DHAP • **ARM 2:** MEDI-551 dose level 2 and ICE/DHAP • **ARM 2:** Rituxan + ICE/DHAP Open label study	• ORR, including Complete Response (CR) or Partial Response (PR)	• FSI Q3 11 • Restart Q2 12 • Est completion Q3 16
Adults with relapsed or refractory B-cell malignancies	**Phase I/II** NCT00983619	N = 91	• Dose-escalation study IV Open label study	• MTD and efficacy	• FSI Q2 10 • Est completion Q1 18
Adults with relapsed or refractory B-cell malignancies	**Phase I** NCT01957579	N = 18	• Dose-escalation study IV Conducted in Japan	• MTD and efficacy	• FSI Q2 11 • Est completion Q4 14
Adults with Newly Diagnosed multiple myeloma	**Phase I** NCT01861340	N = 15	• Lenalidomide, Dexamethasone and MEDI-551 IV	• Effect of Lenalidomide, dexamethasone and MEDI-551 on multiple myeloma cancer stem cells	• FSI Q2 14 • Est completion Q3 15
Adults with relapsed or refractory B-cell malignancies	**Phase I/II** NCT00983619	N = 193	• **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)	• MTD and efficacy • Safety and tolerability • Clinical activity of MEDI-551	• FSI Q2 14 • Est completion Q1 18

Immuno-oncology portfolio

Monotherapy early development programme

	Patient Population	Phase Study	# of Patients	Design	Endpoint(s)	Status
PD-1 (MEDI0680)	**Solid tumours**	**Phase Ia** NCT02013804	N = 72	• Dose Escalation (3+3) & Expansion Study • Study amended to explore q2w schedule and doses > 10mg/kg	• Safety and tolerability	• FSI Q4 13 • LSI Q4 14 (escalation) • LSI Q3 15 (expansion) • Est. completion date Q3 15
PD-L1 (MEDI4736)	**Myelodysplastic syndrome**	**Phase I** NCT02117219	N = 70	Dose-escalation and dose-expansion study • **ARM 1:** MEDI4736 IV	• Safety and tolerability • Secondary endpoints include duration of response, progression free survival and overall survival	• FSI Q2 14 • LSI Q1 15 (40 pts) • LSI Q2 15 (70 pts) • Est completion date Q4 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 = 204	• **Dose Escalation:** minimum 5 cohorts exploring various treme Q4w and MEDI4736 IV Q4w dose combinations, higher dose levels and alternate q2 schedule added with amendment • **Dose Expansion:** MTD for the combination in escalation to be explored in expansion North American study centers, exploration of 1-2 ex-US countries for expansion	• Safety • Optimal biologic dose for the combination • Secondary endpoints include Antitumour activity, PK and immunogenicity	• FSI Q4 13 • LSI Q3 15 • Est completion Q1 17 • Abstract accepted for publication only Q2 14 (ASCO) • Est external presentation Q3 14

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:** • **Cohort A** – dabrafenib 150mg BiD/ trametinib 2mg QD/ MEDI4736 IV • **Cohort B** – trametinib 2mg QD/ MEDI4736 IV • **Cohort C** – trametinib 2mg QD/ MEDI4736 IV • **Dose Expansion:** Each cohort will be expanded at the MTD to enroll a total of 20 subjects per cohort Global study – 2 countries	• 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	• FSI Q4 13 • LSI Q4 15 • Est completion Q1 17

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 = 29	**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	• 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	• FSI Q1 14 • LSI Q1 15 • Est completion date Q4 17

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** • MEDI4736 IV + MEDI0680 IV **Dose-expansion phase at selected dose from dose-escalation phase** • MEDI4736 IV + MEDI0680 IV recommended dose	• Safety • Determination of MTD • Secondary endpoints include tumour response such as objective response rate, disease control rate, progression-free survival, duration of response, overall survival, immunogenicity, pharmacokinetics, pharmacodynamics	• FSI Q2 14 • LSI Q3 15 • Est completion date Q1 17

Anti-CTLA-4 (tremelimumab) + *Iressa* (gefitinib)

NSCLC development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
EGFRm+ NSCLC	**Phase I** **NCT02040064**	N = 24	**Cohort 1**: Tremelimumab IV 3 mg/kg q4w plus Gefitinib 250 mg QD, 6 patients (+ 6 patients if 3 mg/kg is the MTD) **Cohort 2**: Tremelimumab IV 6 mg/kg q4w plus Gefitinib 250 mg QD, 6 patients (+ 6 patients if 6 mg/kg is the MTD) **Cohort 3**: Tremelimumab IV 10 mg/kg q4w plus Gefitinib 250 mg QD, 6 patients (+ 6 patients if 10 mg/kg is the MTD)	• Safety and tolerability • Secondary endpoints include tumour response; RECIST, disease control rate, PFS	• FSI Q1 14 • Est completion date Q2 15

Oncology biologics early development

Solid tumors development programme

	Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Anti-Ang2 mAb (MEDI3617)	**Solid tumors and ovarian cancer**	**Phase I** **NCT01248949**			• Safety and tolerability	• Recruitment Complete
			N = 15-24	• MEDI3617 + bevacizumab dose escalation, administered Q3w, IV (US only)		
			N = 9-12	• MEDI3617 + paclitaxel dose escalation, IV (US only)		
			N = 9-12	• MEDI3617 + carboplatin + paclitaxel dose escalation, IV (US only)		
			N = 15-24	• MEDI3617 + bevacizumab dose escalation, administered Q2w , IV (US only)		
			N = 25	• MEDI3617 single-agent expansion in ovarian cancer patients, IV (US only)	• Safety and tolerability • > 20% efficacy signal	• FSI Q4 12 • LSI Q4 14 • Est completion date Q3 15 • External presentation Q2 14 (ASCO)
Anti-IGF ligand mAb (MEDI-573)	**Patients with HR+ HER2-, 1st line, metastatic breast cancer taking aromatase inhibitors**	**Phase I/II** **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 study completion Q4 15 • Est external presentation 2015

Oncology biologics early development

Solid tumours development programme

	Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Anti-CEA BiTE mAb (MEDI-565)	**Adults with gastrointestinal (GI) adenocarcinoma with no available standard or curative treatments.** **Refractory pancreatic, colorectal and gastro-esophageal cancers**	**Phase I** **NCT01284231** **Partnered**	N = 51 max N = 60 max, 20 in each cohort	• Dose-escalation (3+3), IV • Dose expansion study, IV	• MTD and safety profile	• FSI Q4 10 • Est completion Q3 17
Anti-DLL4 mAb (MEDI0639)	**Adults with advanced solid tumors including SCLC**	**Phase I** **NCT01577745**	N = up to 28 N = up to 32	• Dose-escalation study (3+3); IV • Combination dose-escalation and expansion study; IV	• MTD and safety profile • MTD and safety profile in combination	• FSI Q2 12 • LSI Q4 15 • Est completion Q4 16 • Est external presentation 2015

Tralokinumab (anti-IL-13)

Asthma & IPF development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Adults with Uncontrolled Severe Asthma	**Phase III** NCT02161757	N = 1140	• Cohort 1: • **ARM 1:** Tralokinumab dose regimen 1 SC • **ARM 2:** Placebo SC • Cohort 2 : • **ARM 1:** Tralokinumab dose regimen 2 SC • **ARM 2:** Placebo SC • 2:1 randomisation in both cohorts Global study – 4 countries	Primary Endpoint • Annual asthma exacerbation rate Key Secondary Endpoints: • 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)	• Planned FSI Q3 14 • Primary completion Q2 17
Adults with Uncontrolled Severe Asthma	**Phase III** NCT02194699	N = 770	• **ARM 1:** Tralokinumab SC • **ARM 2:** Placebo SC • 1:1 randomisation Global study – 11 countries including Japan	Primary Endpoint • Annual asthma exacerbation rate Key Secondary Endpoints: • 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)	• Planned FSI Q4 14 • Primary completion Q3 17

Tralokinumab (anti-IL-13) continued…

Asthma & IPF development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Adults with Idiopathic Pulmonary Fibrosis	**Phase II** NCT01629667	N = 186	• **ARM 1:** Tralokinumab high dose • **ARM 2:** Tralokinumab low dose • **ARM 3:** Placebo High dose: low dose: placebo (1:1:1) Global study – 6 countries	• Change from baseline in percent-predicted forced vital capacity at week 72 Key Secondary Endpoints: • No. of patients with disease progression • Safety and tolerability • Tralokinumab serum concentration	• FSI Q4 12 • Est primary completion Q1 17
Japanese Adults with Idiopathic Pulmonary Fibrosis	**Phase II** NCT02036580	N = 20	<u>Cohort 1:</u> • **ARM 1:** Tralokinumab high dose • **ARM 2:** Placebo <u>Cohort 2 :</u> • **ARM 1:** Tralokinumab low dose • **ARM 2:** Placebo 8:2 randomisation in both cohorts Japan only study	• Safety and tolerability Key Secondary Endpoints: • Tralokinumab serum concentration • Immunogenicity	• FSI Q1 14 • Est completion Q4 15

Anti-TSLP (MEDI9929/AMG 157)

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	• **ARM 1:** Placebo • **ARM 2:** Low dose MEDI9929 SC • **ARM 3:** Medium dose MEDI9929 SC • **ARM 4:** High dose MEDI9929 SC	• Reduction in the annualized asthma exacerbation rate (AER) measured at Week 52	• FSI Q2 14 • LSI Q3 15 • Est completion Q4 16
Healthy adult male Japanese subjects	**Phase I** NCT01913028 **Partnered**	N = 24	• **ARM 1:** SAD MEDI9929 SC • **ARM 2:** Placebo	• Safety and tolerability of single ascending subcutaneous doses	• Completed • Final report Q2 14

Mavrilimumab (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)	• **ARM 1:** Mavrilimumab 30 mg SC • **ARM 2:** Mavrilimumab 100 mg SC • **ARM 3:** Mavrilimumab 150 mg SC • **ARM 4:** Placebo Global study (ex-US) on MTX background	• DAS28 response at wk12 • ACR 20 at wk 24	• FSI Q3 12 • LSI Q2 13 • Completed Q1 14 • Est external presentation planned 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 = 135 (final)	• **ARM 1:** Mavrilimumab 100 mg SC q2w • **ARM 2:** golimumab Global study (ex-US) on MTX background	• ACR 20/50/70 at wk 24 • DAS28 remission • Function (HAQ-DI)	• FSI Q1 13 • LSI Q2 14 • Est completion Q1 15 • Est external presentation beyond planning horizon
Eligible RA patients from Explorer 1 & 2	**Phase II EARTH Explorer X** **NCT01712399**	N = 400 projected	• **ARM 1:** Mavrilimumab 100 mg SC q2w Open label extension of Explorer 1 & 2 Global study (ex-US) on MTX background	• Sustained disease improvement & safety	• FSI Q1 13 • OLE, ongoing until regulatory filing • Est external presentation beyond planning horizon

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 = 431	• **Arm 1:** 200 mg IV MEDI-545 q2w for 4 wks then q4wk for 44 wks • **Arm 2:** 600 mg IV MEDI-545 q2w for 4 wks then q4wk for 44 wks • **Arm 3:** 1200 mg IV MEDI-545 q2w for 4 wks then q4wk for 44 wks • **Arm 4:** placebo IV q2w for 4 wks then q4wk for 44 wks	• Proportion of subjects achieving a response in an SLE responder index at 12 months	• FSI Q2 11 • Est completion Q2 14 • Est external presentation Q4 14 (ACR)
SLE, DM or PM patients	**Phase II** NCT00979654	N = 260	• 600 mg IV Medi-545 Open label study	• Evaluate long-term safety and tolerability of multiple IV doses of MEDI-545	• FSI Q3 10 • Est completion Q1 15

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 = 300	• **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	• Response in SLE responder index at 6 months	• FSI Q1 12 • Est completion Q2 15 • Estimated external presentation beyond planning horizon
Moderate-severe SLE patients	**Phase II** NCT01753193	N = 240	• **ARM 1:** MEDI-546, IV q4w for 104 weeks	• Open-label extension to evaluate long-term safety and tolerability	• FSI Q1 13 • Est completion Q3 17

Japanese SLE patients	**Phase II**
	NCT01559090
		N = 17	• **ARM 1:**
			  • 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:**
			  • 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:**
			  • Stage I: 1000mg IV MEDI-546, single dose and multiple doses q4w for 48 wks.
			  • Stage II: 1000mgIV, multiple doses q4w for 104 wks
				• Safety profile of MEDI-546: adverse events, vital signs, clinical laboratory assessments and ECGs	• FSI Q1 12
					• Est completion Q3 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 = 40	**Dose escalation study:** • **ARM 1:** MEDI5872 SC • **AMR 2:** placebo SC Global study – 8 countries	• Safety and tolerability • Lupus Arthritis Response Rate	• FSI Q2 12 • LSI Q2 15 • Est. Completion Q2 16

Anti-Staph AT (MEDI4893)

Phase I clinical development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Healthy Adults	**Phase I** NCT01769417	N = 33	• Randomized, Double-blind, Placebo-Controlled, Dose-Escalation Study • Route of administration: intravenous	• Evaluate the Safety, Tolerability, and Pharmacokinetics of	• Dosing completed

LAIV RSV Paediatric Vaccine (MEDI-559)

Phase I/IIa clinical development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Healthy 6-24 mo prevention of RSV disease in infants	**Phase I/IIa** NCT00767416	N = 116	• Randomized, Double-Blind, Placebo-Controlled Study • Route of administration: intranasal	• Evaluate the Safety, Tolerability, Immunogenicity and Viral Shedding	• 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)

Phase I clinical development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Healthy adults	**Phase I** **NCT01175122** **NCT00922259** **NCT00516035** **NCT00853255** **NCT01674205** **NCT00110279** **NCT01443663** **NCT00347672** **NCT00488046** **NCT01534468** **NCT00722774** **NCT00734175** **NCT00380237** **Partnered**	Varies	• Administration of live attenuated influenza virus vaccine for the following strains: H2N2, H2N3, H5N1, H6N1, H7N3, H7N7, H9N2 (separate studies for each strain) Nasal administraion US only	• Safety and Immunogenicity	• Study Starts: 2005-2012 • Primary Completion Dates: 2005-2012

RSV sF+GLA-SE (MEDI7510)

Phase I development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Adults ≥ 60 yrs	**Phase I** NCT02115815	N = 144	• **ARM 1:** MEDI7510 IM • **ARM 2:** RSV sF IM • **ARM 3:** Placebo IM	• Safety and tolerability • Humoral and cell-mediated immune responses	• FSI Q2 14 • Est completion Q3 14

Anti-RSV mAb-YTE (MEDI8897)

Phase I clinical development programme

Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Healthy Adults	**Phase Ia** **NCT02114268**	N = 136	• **ARM 1:** MEDI8897 IV & IM • **ARM 2:** Placebo	• Evaluate Safety, Tolerability, PK and ADA	• FSI Q2 14 • Est completion Q4 14

Neuroscience biologics early development

Phase I development programmes

	Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Anti-amyloid beta mAb (MEDI1814)	**Alzheimers Disease & Healthy Elderly**	**Phase I** NCT02036645	N = 121	• SAD & MAD • Up to 10 iv cohorts are planned vs placebo • 2 SC cohorts are planned vs placebo US only	• Safety, tolerability	• FSI Q2 14 • LSI Q2 16 • Est. Completion date Q4 16 • Est. external presentation beyond planning horizon
Anti-CD19 mAb (MEDI-551)	**Multiple sclerosis**	**Phase I** NCT01585766	N = 28	• SAD (IV/SC) Global study	• Safety, PK	• Study is recruiting • Est. completion date Q1 15 • Estimated external presentation beyond planning horizon
Anti-CD40L (MEDI4920)	**Healthy Adults**	**Phase I** NCT02151110	N = 56	• Dose-escalation study, single IV dose	• Safety, tolerability, and pharmacokinetics, anti-drug antibody, inhibition of T-cell dependent antibody response	• FSI Q2 14 • Est completion Q2 15

Gastrointestinal biologics early development

UC & CD development programme

	Patient Population	Phase Study	# of patients	Design	Endpoint(s)	Status
Anti-α4β7 mAb (MEDI7183)	**Moderate to Severe Ulcerative Colitis**	**Phase II** **NCT01694485** **Partnered**	N = 360	• **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)	• FSI Q4 12 • Enrollment suspended due to logistical issues re-started Q4 13 • LSI Q4 14 • Est completion Q1 15 • Est external presentation 2016
	Moderate to Severe Crohn's Disease	**Phase II** **NCT01696396** **Partnered**	N = 252	• **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)	• FSI Q4 12 • Enrollment suspended due to logistical issues re-started Q4 13 • LSI Q4 14 • Est completion Q2 15 • Est external presentation 2016
	Japanese subjects with moderate to severe Ulcerative Colitis	**Phase II** **NCT01959165** **Partnered**	N = 48	• **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)	• FSI Q4 13 • LSI Q2 14 • Est completion Q1 15
Anti-IL-23 mAb MEDI2070	**Patients with Moderate to Severe Crohn's Disease**	**Phase II** **NCT01714726** **Partnered**	N = 120	• **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	• FSI Q1 13 • LSI Q1 14 • Est completion Q2 14 • Est external presentation Q4 14

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