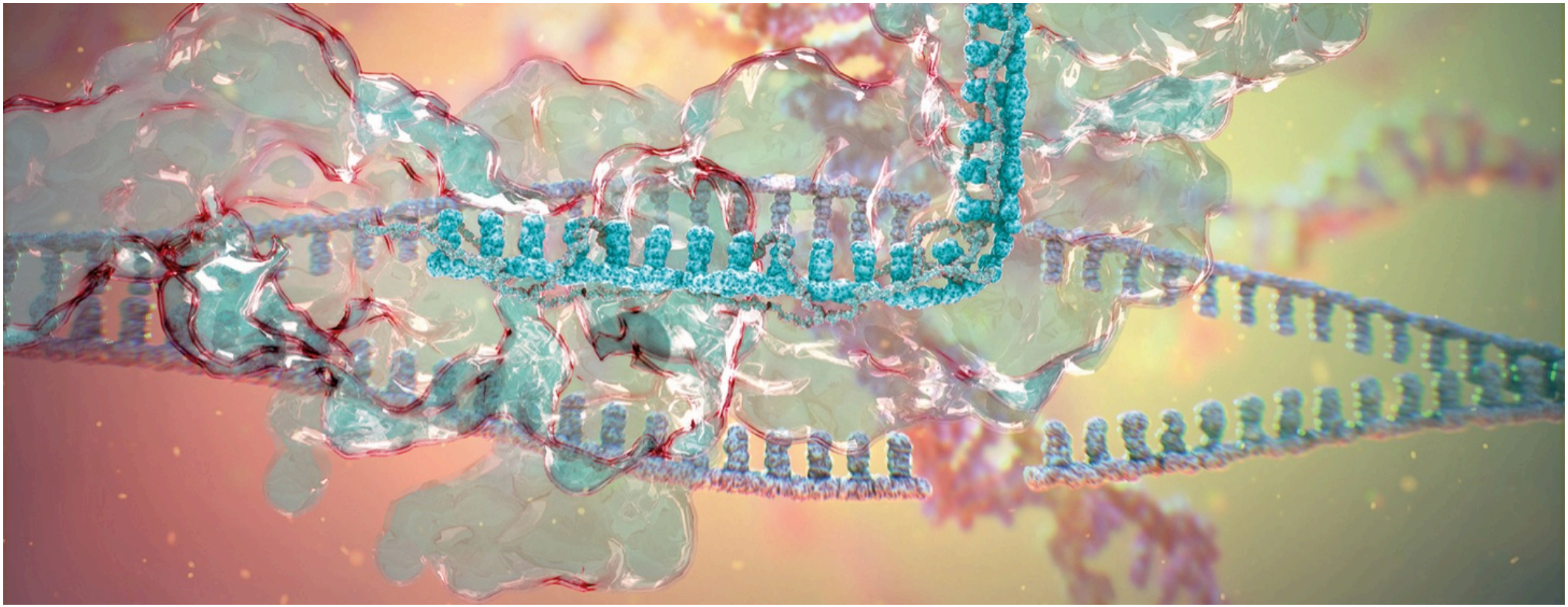
Clinical Trials Appendix
Q4 2015 Update

AstraZeneca
What science can do



The following information about 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 of 31 December 2015, unless otherwise specified.

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.

List of abbreviations

AEs	Adverse Events
ASA	Acetylsalicylic Acid
BiD	Twice Daily
CE	Clinically Evaluable
cMITT	Clinical Modified Intent-To-Treat population
DLT	Dose Limiting Toxicity
FEV	Forced Expiratory Volume
FPD	First Patient Dosed
HIF-PHI	Hypoxia-inducible factor prolyl hydroxylase inhibitor
ICS	Inhaled Corticosteroid
IM	Intra-muscular
IR	Immediate Release
IV	Intra-venous
LABA	Long Acting Beta Agonist
LAMA	Long Acting Muscarinic Agonist
LCM	Lifecycle Management
LPD	Last Patient Dosed
MAD	Multiple Ascending Dose Study
MDI	Metered Dose Inhaler
MITT	Modified Intent-To-Treat population
mMITT	Microbiological Modified Intent-To-Treat population
MTD	Maximum Tolerated Dose
MTX	Methotrexate
NME	New Molecular Entity
OLE	Open Long Term Extension
ORR	Objective Response Rate
OS	Overall Survival
PARP	Poly ADP ribose polymerase
PFS	Progression Free Survival
Q2W	Every Other Week
Q3W	Every Three Weeks
Q4W	Every Four Weeks
Q8W	Every Eight Weeks
QD	Once Daily
SAD	Single Ascending Dose Study
SC	Sub-cutaneous
TiD	Three Times a Day
TOC	Test of Cure
XR	Extended Release

Movement since Q3 2015

New to Phase I	New to Phase II	New to Pivotal Study	New to Registration
NMEs **AZD0156** ATM serine/threonine kinase solid tumours **AZD2811** Aurora B kinase solid tumours **AZD4076** miR103/107 NASH **AZD8871** MABA COPD **AZD9567** oral SGRM rheumatoid arthritis **MEDI1873** GITR solid tumours **MEDI4166** PCSK9/GLP-1 diabetes/cardiovascular **MEDI4276** HER2 solid tumours **MEDI9197** TLR 7/8 solid tumours **Additional indications** **anifrolumab#** IFN-alphaR mAb systemic lupus erythematosus SC **lesinurad+allopurinol** URAT-1+XO chronic treatment of hyperuricemia in patients with gout	**NMEs** **AZD3759 or *Tagrisso* (AZD9291) BLOOM** EGFR brain metastases in advanced EGFRm NSCLC **MEDI6012** LCAT ACS **MEDI8852** Influenza A **Additional indications** **anifrolumab#** IFN-alphaR mAb lupus nephritis	**NME** **acalabrutinib#[1]** B-cell blood cancers **Additional indications** ***Tagrisso* (AZD9291) ADAURA** EGFR adjuvant EGFRm NSCLC ***Tagrisso* (AZD9291) AURA 3[2]** ≥2nd-line advanced EGFRm T790M NSCLC **durvalumab#+tremelimumab ALPS¶** PD-L1+CTLA-4 metastatic pancreatic ductal carcinoma **durvalumab#+tremelimumab DANUBE** PD-L1+CTLA-4 1st-line bladder **durvalumab#+tremelimumab EAGLE** PD-L1+CTLA-4 2nd-line SCCHN **durvalumab#+tremelimumab KESTREL** PD-L1+CTLA-4 1st-line SCCHN **durvalumab#+tremelimumab NEPTUNE** PD-L1+CTLA-4 1st-line NSCLC	**NMEs** **brodalumab [US, EU]** psoriasis **MEDI-550** pandemic influenza virus vaccine[3] **ZS-9** potassium binder hyperkalaemia **Lifecycle Management** **linaclotide [CN][4]** irritable bowel syndrome with constipation
Removed from Phase I	**Removed from Phase II**	**Removed from Phase III**	**Removed from Registration**
NMEs **AZD9977** MCR diabetic kidney disease **Additional indications** **durvalumab sequencing study** PD-L1 NSCLC	**NMEs** **AZD4901[5]** NK3 receptor polycystic ovarian syndrome **AZD5847** oxazolidinone antibacterial tuberculosis **Additional indicatons** **tralokinumab** IL-13 idiopathic pulmonary fibrosis	**Additional indications** **durvalumab# ATLANTIC¶** PD-L1 3rd-line NSCLC (PD-L1 positive)	**NME** ***Tagrisso* (AZD9291)[6]** ≥2nd-line advanced EGFRm T790M NSCLC ***Zurampic* (lesinurad)[6]** chronic treatment of hyperuricemia in patients with gout

Partnered and/or in collaboration
¶ Registrational Phase II/III study
[1] Acerta Pharma agreement completed Q1 2016; [2] Trial commenced Q3 2014; [3] MEDI-550 does not count toward late-stage NME totals (MAA submitted to EMEA December 2015);
[4] Regulatory submission accepted in China in January 2016; [5] Divested; [6] Approved Q4 2015

Q4 2015 New Molecular Entity (NME)[1] Pipeline

RIA | CVMD | Oncology | Infection, Neuroscience, Gastrointestinal

Phase I
35 New Molecular Entities

Small molecule
- **AZD1419#** TLR9 asthma
- **AZD7986** DPP1 COPD
- **AZD8999** MABA asthma/COPD
- **AZD8871** MABA COPD
- **AZD9567** SGRM RA
- **AZD4076** miR103/107 NASH
- **AZD0156** ATM solid tumours
- **AZD2811#** Aurora solid tumours
- **AZD5312#** androgen receptor prostate
- **AZD6738** ATR solid tumours
- **AZD8186** PI3Kβ solid tumours
- **AZD8835** PI3Kα solid tumours
- **AZD9150#** STAT3 haems & solids
- **AZD9496** SERD ER+ breast
- **MEDI9197#** TLR 7/8 solid tumours
- **ATM AVI#** BL/BLI SBI
- **AZD8108** NMDA suicidal ideation

Large molecule
- **MEDI4920** CD40L-Tn3 pSS
- **MEDI5872#** B7RP1 SLE
- **MEDI7836** IL-13 asthma
- **anifrolumab#** IFNαR SLE SC
- **MEDI0382** GLP-1/glucagon diabetes/obesity
- **MEDI4166** PCSK9/GLP-1 diabetes/CV
- **MEDI8111** Rh-Factor II trauma/bleeding
- **MEDI0562#** hOX40 solid tumours
- **MEDI0639#** DLL-4 solid tumours
- **MEDI0680** PD-1 solid tumours
- **MEDI1873** GITR solid tumours
- **MEDI3617#** ANG-2 solid tumours
- **MEDI4276** HER2 solid tumours
- **MEDI-565#** CEA BITE GI tumours
- **MEDI6383#** Ox40 FP solid tumours
- **MEDI9447** CD73 solid tumours
- **MEDI1814** amyloidβ Alzheimer's
- **MEDI3902** Psl/PcrV pseudomonas

Phase II
27 New Molecular Entities

Small molecule
- **AZD7594** Inhaled SGRM asthma
- **abediterol (AZD0548)** LABA asthma/COPD
- **AZD7624** Inhaled p38 inhibitor COPD
- **RDEA3170** URAT-1 hyperuricemia/gout
- **AZD3759 or Tagrisso (AZD9291) BLOOM**
- **AZD1775#** Wee-1 ovarian
- **AZD2014** mTOR 1/2 solid tumours
- **AZD4547** FGFR solid tumours
- **AZD5363#** AKT breast cancer
- **savolitinib#** MET pRCC
- **AZD3241** MPO Multiple System Atrophy
- **AZD3293#** BACE Alzheimer's
- **CXL#** BLI/cephalosporin MRSA

Large molecule
- **anifrolumab#** IFNαR lupus nephritis
- **AZD9412#** Inhaled βIFN asthma/COPD
- **mavrilimumab#** GM-CSFR rheumatoid arthritis
- **MEDI2070#** IL-23 Crohns
- **MEDI-551#** CD19 neuromyelitis optica
- **abrilumab#** α4β7 Crohns/ulcerative colitis
- **MEDI9929#** TSLP asthma/atopic dermatitis
- **MEDI6012** LCAT ACS
- **MEDI-551#** CD19 DLBCL
- **MEDI-573#** IGF metastatic breast cancer
- **MEDI4893** staph alpha toxin SSI
- **MEDI7510** sF+GLA-SE RSV prevention
- **MEDI8852** influenza A treatment
- **MEDI8897#** RSV passive prophylaxis

Phase III
10 New Molecular Entities

Small molecule
- **PT010** LABA/LAMA/ICS COPD
- **roxadustat#** HIFPH anaemia CKD/ESRD
- **acalabrutinib ψ** BTK B-cell blood cancers
- **selumetinib# SELECT-1** MEK 2L KRAS+ NSCLC

Large molecule
- **anifrolumab# TULIP** IFNαR SLE
- **benralizumab#** IL-5R severe asthma
- **tralokinumab** IL-13 severe asthma
- **durvalumab# HAWK¶** PD-L1 2L SCCHN
- **moxetumomab#** CD22 HCL
- **tremelimumab DETERMINE¶** CTLA-4 mesothelioma

Applications Under Review
5 New Molecular Entities

Small molecule
- **PT003 PINNACLE** LABA/LAMA COPD
- **ZS-9** potassium binder hyperkalaemia
- **cediranib ICON 6** VEGF PSR ovarian
- **CAZ AVI#** BLI/cephalosporin SBI/cIAI/cUTI

Large molecule
- **brodalumab#** IL-17R psoriasis
- **MEDI-550** pandemic influenza virus vaccine

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

Partnered and/or in collaboration; ¶ Registrational P2/3 study; ψ Completion of the agreement with Acerta Pharma Q1 2016

† MEDI-550 does not count toward late-stage NME totals (submitted to EMEA December 2015)

Q4 2015 Lifecycle Management (LCM)[1] Pipeline

RIA | CVMD | Oncology | Infection, Neuroscience, Gastrointestinal

Phase I
3 Projects

Small molecule

- lesinurad+allopurinol FDC — URAT-1+XO gout

Large molecule

- anifrolumab# — IFNαR SLE SC
- durvalumab# — PD-L1 solid tumours

Phase II
7 Projects

Small molecule

- PT010 — LABA/LAMA/ICS asthma
- Epanova+Farxiga/Forxiga — NASH
- Lynparza — PARP prostate cancer
- selumetinib# — MEK 2L KRAS wt NSCLC

Large molecule

- anifrolumab# — IFNαR lupus nephritis
- tralokinumab — IL-13 atopic dermatitis
- durvalumab# — PD-L1 solid tumours

Phase III
26 Projects

Small molecule

- Symbicort BAI — asthma/COPD
- Symbicort SYGMA — as needed in mild asthma
- Brilinta/Brilique EUCLID — PAD outcomes
- Brilinta/Brilique HESTIA — paeds w/ sickle cell
- Brilinta/Brilique SOCRATES — stroke outcomes
- Brilinta/Brilique THEMIS — diabetes & CAD outcomes
- Bydureon wkly suspension — Type 2 diabetes
- Bydureon EXSCEL — outcomes
- Epanova STRENGTH — outcomes
- Farxiga/Forxiga — Type 1 diabetes
- Farxiga/Forxiga DECLARE — outcomes
- Tagrisso (AZD9291) ADAURA — EGFR adj. EGFRm NSCLC
- Tagrisso (AZD9291) AURA 3 — EGFR T790M NSCLC >2L
- Tagrisso (AZD9291) FLAURA — EGFR 1L adv. EGFRm NSCLC
- Faslodex FALCON — oestrogen receptor 1L adv. breast
- Lynparza GOLD — PARP 2L gastric cancer
- Lynparza OlympiAD — PARP gBRCA metastatic breast
- Lynparza POLO — PARP pancreatic cancer
- Lynparza SOLO-1 — PARP 1L BRCAm ovarian
- Lynparza SOLO-2 — PARP >2L BRCAm PSR ovarian
- Lynparza SOLO-3 — PARP BRCAm PSR ovarian
- Lynparza OlympiA — PARP gBRCA adjuvant breast
- selumetinib# ASTRA — MEK 2L diff. thyroid
- Nexium (CN only) — stress ulcer prophylaxis

Large molecule

- benralizumab# — IL-5R COPD
- durvalumab# PACIFIC — PD-L1 Stage 3 NSCLC

Applications Under Review
3 Projects

Small molecule

- saxa+dapa FDC — diabetes
- CAZ AVI# — BLI/cephalosporin HAP/VAP
- linaclotide# (CN only) — IBS-c

Large molecule

Oncology Combinations

Phase I
7 Projects

- durvalumab#+dabrafenib+trametinib¥ — PD-L1+BRAF+MEK melanoma
- durvalumab#+Iressa — PD-L1+EGFR NSCLC
- durvalumab#+MEDI0680 — PD-L1+PD-1 solid tumours
- durvalumab#+MEDI6383# — PD-L1+Ox40 agonist solid tumours
- durvalumab#+tremelimumab — PD-L1+CTLA-4 solid tumours
- MEDI-551#+rituximab — CD19+CD20 haems
- Tagrisso (AZD9291) combo# TATTON — EGFR+PD-L1/MEK/MET NSCLC

Phase II
2 Projects

- AZD5069+durva# or AZD9150#+durva# — (CXCR2 or STAT3)+PD-L1 SCCHN
- durvalumab#+tremelimumab — PD-L1+CTLA-4 gastric cancer

Phase III
9 Projects

- durvalumab# +tremelimumab ALPS¶ — PD-L1+CTLA-4 1L metastatic pancreatic
- durvalumab# +tremelimumab ARCTIC — PD-L1+CTLA-4 3L NSCLC
- durvaluma# +tremelimumab CONDOR¶ — PD-L1+CTLA-4 2L SCCHN
- durvalumab# +tremelimumab DANUBE — PD-L1+CTLA-4 1L bladder
- durvalumab# +tremelimumab EAGLE — PD-L1+CTLA-4 2L SCCHN
- durvalumab# +tremelimumab KESTREL — PD-L1+CTLA-4 1L SCCHN
- durvaluma# +tremelimumab MYSTIC — PD-L1+CTLA-4 1L NSCLC
- durvalumab# +tremelimumab NEPTUNE — PD-L1+CTLA-4 1L NSCLC
- Tagrisso (AZD9291)+durva# CAURAL — EGFR T790M NSCLC >2L

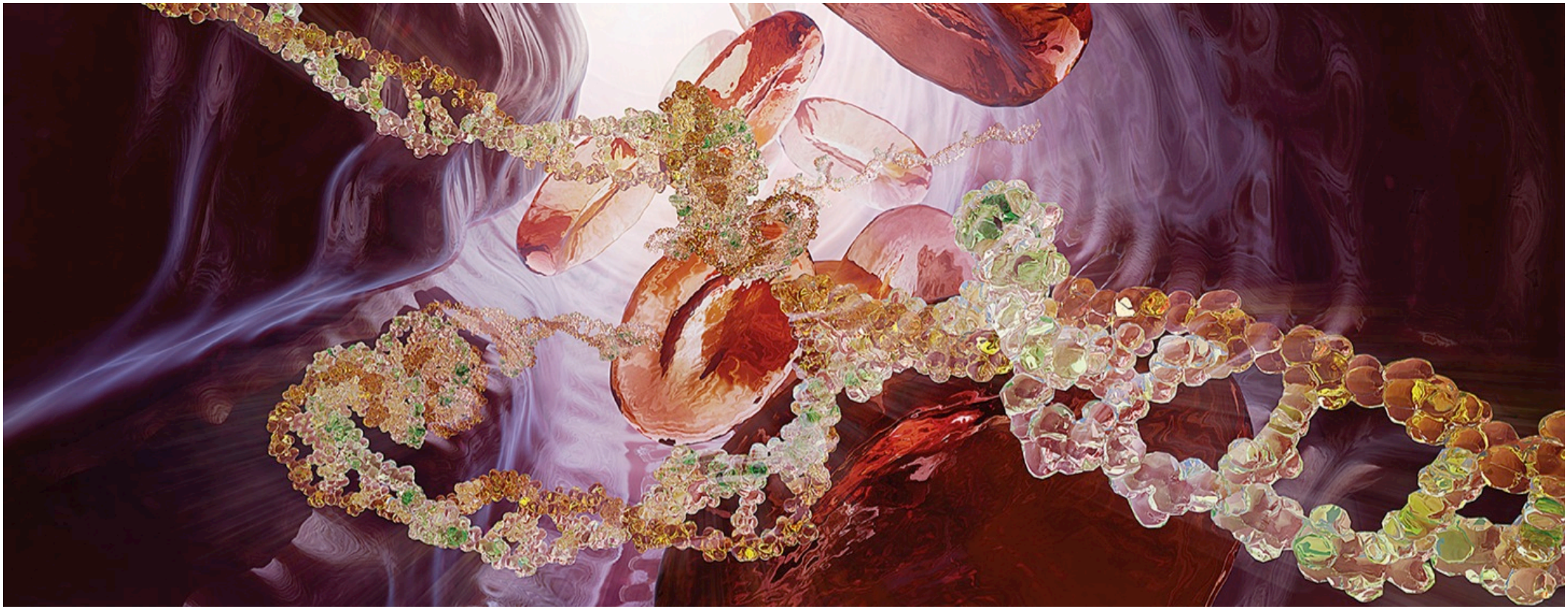
[1] Includes significant LCM projects and parallel indications for assets in P3 or beyond. Excludes LCM projects already launched in a major market

Partnered and/or in collaboration; ¶ Registrational P2/3 study; ¥ MedImmune-sponsored study in collaboration with Novartis

AstraZeneca

AstraZeneca
What science can do

Lifecycle management (new uses of existing medicines)



Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Symbicort (ICS/LABA)

Mild asthma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **SYGMA1** **NCT02149199**	Patients in need of GINA step 2 treatment	N = 3,750	• **Arm 1**: Symbicort Turbuhaler 160/4.5 µg 'as needed' + Placebo Pulmicort Turbuhaler 200 µg bid • **Arm 2:** Pulmicort 200 µg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler 'as needed' • **Arm 3:** 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	• FPD: Q4 14 • LPD: 2017 • Est. completion: 2017 • Est. topline results: 2017
Phase III **SYGMA2** **NCT02224157**	Patients in need of GINA step 2 treatment	N = 4,114*	• **Arm 1**: Symbicort Turbuhaler 160/4.5 µg 'as needed' + Placebo Pulmicort Turbuhaler 200 µg bid • **Arm 2:** Pulmicort 200 µg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler 'as needed' Global study – 25 countries	• Annual severe asthma exacerbation rate • Time to first severe asthma exacerbation • Average change from baseline in pre-dose FEV1 • Time to study specific asthma related discontinuation	• FPD: Q1 15 • LPD: 2017 • Est. completion: 2017 • Est. topline results: 2017

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

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Eklira/Tudorza (LAMA)

Chronic Obstructive Pulmonary Disease (COPD)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV **NCT02375724** **Partnered: Menarini**	Patients with COPD	N = 224	• **Arm 1**: Aclidinium bromide 400 µg • **Arm 2:** Placebo to aclidinium bromide 400 µg Global Study – 5 countries	• Change from baseline in Overall E-RS Total score (i.e. score over the whole 8 weeks study period) • Change from baseline in Overall E-RS Cough and Sputum domain score • Change from baseline in the LCQ Total score at Week 8. Average change from baseline in pre-dose FEV1	• FPD: Q1 15 • LPD: Q3 15 Clinically completed Est. topline results H1 16 Est. completion date: H1 16
Phase IV **ASCENT** **NCT01966107** **Partnered:** **Forest/Actavis**	Patients with moderate to very severe COPD	N = 4,000	• **Arm 1:** Aclidinium bromide 400 µg • **Arm 2:** Placebo to aclidinium bromide 400 µg Global Study – 2 countries	• Time to first Major Adverse Cardiovascular Event (MACE). Up to 36 Months • Rate of moderate or severe COPD exacerbations per patient per year during the first year of treatment. • Rate of hospitalizations due to COPD exacerbation per patient per year during the first year of treatment • Time to first Major Adverse Cardiovascular Event (MACE) or other serious cardiovascular events of interest. Up to 36 Months	• FPD: Q4 13 • LPD: H2 16 • Est. completion date: 2018
Phase IV **NCT02153489** **Partnered:** **Almirall**	Patients with stable moderate and severe COPD	N = 30	• **Arm 1:** Aclidinium bromide 400 µg • **Arm 2:** Placebo to Aclidinium bromide 400 µg Local Study – 1 country	• Change from baseline in normalized forced expiratory volume in one second (FEV1). Week 3. FEV1 over the 24-hour period (AUC0-24) will be measured following morning administration • Adverse events. Week 5. A follow up telephone call will be made 14 days after the last study drug administration (for completed patients) or premature discontinuation visit (when applicable) to record adverse events	• FPD: Q2 14 • LPD: Q1 15 • Topline results: Q4 15

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Duaklir (LAMA/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV **ACTIVATE** **NCT02424344** **CO-FUNDED: Menarini**	Patients with moderate to COPD	N = 268	• **Arm 1:** Aclidinium/formoterol FDC 400/12 µg • **Arm 2:** Placebo to aclidinium/formoterol FDC 400/12 µg Global Study – 5 Countries	• Change from baseline in trough Functional Residual capacity (FRC) after 4 weeks of treatment • Change from baseline in Endurance Time (ET) during constant work rate cycle ergometry to symptom limitation at 75% of Wmax after 8 weeks of treatment • Percentage of inactive patients (<6000 steps per day) after 8 weeks on treatment	• FPD: Q2 15 • LPD: H1 16 • Est. completion date: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Daxas/DaliResp (oral PDE4 inhibitor)

Chronic Obstructive Pulmonary Disease (COPD)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV RESPOND NCT01443845	COPD	N = 2,354	• 52W, Randomised, DB with Roflumilast 500µg OD vs Placebo	• Rate of Moderate or Severe COPD Exacerbations/Patient/Year	• Ongoing not recruiting • Est. completion date: H1 16
Phase IV OPTIMISE NCT02165826	COPD	N = 1,323	• 12W, Randomized, DB to evaluate Tolerability and PK of Roflumilast 500µg OD with an Up-titration Regimen during the first 4Ws	• Discontinuation rate on Roflumilast 500µg QD due to any reason	• Completed • Est. results: mid-2016
Phase IIIb ROBERT NCT01509677	COPD	N = 158	• 16W, Randomized, Placebo-controlled, DB, Parallel-group trial to Assess the Anti-inflammatory Effects of Roflumilast	• Number of inflammatory cells CD8+ in bronchial biopsy tissue specimen (sub-mucosa) measured at randomisation visit V2 and at the end of the intervention period (V6)	• Recruiting • Est. results H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Zurampic (lesinurad) (SURI, URAT1 inhibitor)

Gout

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **CLEAR Extension** **NCT01808131**	Gout previously enrolled in studies CLEAR 1 & 2	N = 717	• *Zurampic* 200 or 400 mg QD All patients: SOC allopurinol QD	• Assess the long-term efficacy and safety of *Zurampic* in combination with allopurinol	• FPD: Q1 13 • Study ongoing
Phase III **CRYSTAL Extension** **NCT01808144**	Gout previously enrolled in CRYSTAL study	N = 196	• *Zurampic* 200 or 400 mg QD All patients: febuxostat 80 mg QD	• Assess the long-term efficacy and safety of *Zurampic* in combination with febuxostat	• FPD: Q1 13 • Study ongoing
Phase II **RDEA594-203 Open-label Extension** **NCT01001338**	Gout previously enrolled in Phase II RDEA594-203 study	N = 87	• *Zurampic* 200, 400, or 600 mg QD All patients: SOC allopurinol QD	• Assess the long-term efficacy and safety of *Zurampic* in combination with allopurinol	• FPD: Q1 11 • Study ongoing

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Zurampic (lesinurad)/Allopurinol FDC (SURI, URAT1 inhibitor/XOI inhibitor)

Gout

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **RDEA594-501 Randomized, Open-label, cross-over, relative bioavailability** **NCT02581553**	Healthy Male Subjects	N = 74	**Cohort 1: cross-over, rel. BA** Tx. 1: Lesinurad/allopurinol 200/300 FDC Tx. 2: coadministered lesinurad 200mg + allopurinol 300mg **Cohort 2: cross-over, Food Effect, BA** Tx. 1: Lesinurad/allopurinol 200/300 FDC (fasted) Tx. 2: Lesinurad/allopurinol 200/300 FDC (fed – high fat meal)	• Assess the bioavailability of lesinurad/allopurinol 200/300 FDC tablets relative to coadministered lesinurad and allopurinol tablets in healthy adult male subjects • To assess the effect of a high fat/high calorie meal on the pharmacokinetics of lesinurad/allopurinol 200/300 FDC tablets in healthy adult male subjects	• FPD: Q4 15 • LPD: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Brilinta/Brilique (ADP receptor antagonist)

Cardiovascular

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **PEGASUS** **NCT01225562**	Patients with prior MI	N = 21,000	• **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	• FPD: Q4 10 • LPD: Q4 14 • Completion date: Q1 15
Phase III **EUCLID** **NCT01732822**	Patients with PAD	N = 13,500	• **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	• FPD: Q4 12 • LPD: H2 16 • Est. topline results: H2 16
Phase III **SOCRATES** **NCT01994720**	Patients with stroke or TIA	N = 13,600	• **Arm 1:** Ticagrelor 90 mg BiD • **Arm 2:** ASA 100mg/day *monotherapy trial* Global study – 33 countries	• Composite of non-fatal stroke, non-fatal MI and all cause death	• FPD: Q1 14 • LPD: H1 16 • Est. topline results: H1 16
Phase III **THEMIS** **NCT01991795**	Patients with type 2 diabetes and coronary artery disease without a previous history of MI or stroke	N = 19,000	• **Arm 1**: Ticagrelor 60 mg BiD • **Arm 2:** Placebo BiD *on a background of ASA if not contra indicated or not tolerated* Global study – 42 countries	• Composite of CV death, non-fatal MI and non-fatal stroke	• FPD: Q1 14 • LPD: 2018 • Est. topline results: 2018
Phase III (BE) **NCT02436577**	Japanese healthy volunteers	N = 36	Single dose, Cross-Over • **Arm 1** Ticagrelor OD tablet 90 mg + 150 mL of water • **Arm 2** Ticagrelor OD tablet 90 mg without water • **Arm 3** Ticagrelor IR tablet 90 mg) + 200 mL of water Local study – 1 country	• BE of ticagrelor Dispersible Tablet vs ticagrelor IR tablet	• FPD: Q2 15 • LPD: Q3 15 • Est. topline results: H1 16
Phase III (BE) **NCT02400333**	Caucasian healthy volunteers	N = 36	Single dose, Cross-Over • **Arm 1** Ticagrelor OD tablet 90 mg +200 ml of water • **Arm 2** Ticagrelor OD tablet 90 mg without water • **Arm 3** Ticagrelor OD tablet 90 mg (suspended in water) via nasogastric tube • **Arm 4** Ticagrelor IR tablet 90 mg + 200mL of water Local study – 1 country	• BA/BE of ticagrelor Dispersible Tablet vs ticagrelor IR tablet	• FPD: Q2 15 • LPD: Q3 15 • Est. topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **Japanese Long-term Safety** **NCT02463071**	Japanese patients with hypertriglyceridemia	N = 375	• Epanova 2 g and 4 g vs. Placebo (after meal) daily for 52 weeks Global study – 1 country	• Safety in Japanese patients • % change in triglycerides	• FPD: Q2 15 • LPD: 2017 • Est. topline results: 2017
Phase III **EVOLVE II** **NCT02009865**	Severe hyper-triglyceridaemia	N = 162	• **Arm 1:** Epanova 2g QD • **Arm 2:** Placebo (olive oil) Global study – 7 countries	• Change in serum triglycerides over 12 weeks	• FPD: Q4 13 • LPD: Q4 14 • Completed: Q4 15
Phase III **STRENGTH (CVOT)** **NCT02104817**	Patients with hypertri-glyceridaemia and high CVD risk	N = 13,000	• **Arm 1:** Epanova 4g QD + statin • **Arm 2:** Placebo (corn oil) + statin Global study – 22 countries	• Composite of MACE	• FPD: Q4 14 • Est. topline results: 2019
Phase II **EFFECT I** **NCT02354976**	Overweight patients with hypertriglyceridemia	N = 75	• Epanova 4 g vs. Placebo vs. Fenofibrate 200 mg daily for 12 weeks Global study – 1 country	• Reduction in liver fat content (%) at the end of 12 weeks compared to placebo • Reduction in liver fat content (%) at the end of 12 weeks compared to fenofibrate	• FPD: Q3 15 • LPD: H1 16 • Est. topline results: H1 16
Phase II **EFFECT II** **NCT02279407**	Type 2 DiM Liver fat >5.5%	N = 80	• **Arm 1:** Epanova 4g QD • **Arm 2:** Placebo (olive oil) • **Arm 3:** Epanova 4gm + dapaglifozin 10 mg QD • **Arm 4:** dapaglifozin 10 mg Local study – 1 country	• Reduction in liver fat content (%) at the end of 12 weeks	• FPD: Q1 15 • LPD: Q4 15 • Topline results: H1 16
Phase I **PRECISE** **NCT02370537**	Pancreatic Exocrine Insufficiency (PEI) in patients with type 2 diabetes	N = 66	• **Arm 1**: Epanova© 4g single dose • **Arm 2**: Omacor© 4 g single dose Global study – 6 countries in Europe	• Presence of Pancreatic Exocrine Insufficiency (PEI), Pharmacokinetics of Epanova and Omacor following a single oral dose in patients with different degrees of PEI	• FPD: Q1 15 • LPD: Q3 15 • Est. topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **Microsphere bioavailability** **NCT02359045**	Healthy volunteers	N = 40 Part A N = 42 Part B	• **Arm 1**: D1400147 4g • **Arm 2:** D14000136 4g • **Arm 3**: D14000137 4g • **Arm 4**: Epanova 4g Local study – 1 country	• Rate and extent of absorption of omega-3-carboxylic acids following single-dose oral administration of test formulations A, B and C and reference formulation (Epanova®) under fed and fasted condition, by assessment of AUC, AUC(0-72) and Cmax	• FPD: Q1 15 • LPD: Q3 15 • Completed: Q4 15
Phase I **Japanese food interaction** **NCT02372344**	Healthy male volunteers	N = 42	• Epanova 4 g X 3 separate occasions (fasting, before meal, and after meal) Local study – 1 country	• Effect of food timing (fasting, before meal, and after meal) on pharmacokinetics (AUC, Cmax, AUC0-72)	• FPD: Q1 15 • LPD: Q2 15 • Completed: Q4 15
Phase I **SAD/MAD** **NCT02209766**	Healthy male Japanese and Caucasian subjects	N = 18	• **Arm 1: (Japanese):** Epanova 2g vs. Placebo QD • **Arm 2: (Japanese):** Epanova 4g vs Placebo QD • **Arm 3: (Caucasian):** Epanova 4g vs Placebo Local study – 1 country	• PK of single and multiple doses in healthy male Japanese subjects • Safety/tolerability profile	• FPD: Q3 14 • LPD: Q4 14 • Completed: Q3 15
Phase I **NCT02189252**	Patients with a history of pancreatitis	N = 16	• **Arm 1:** Epanova 4g →Lovaza 4g QD • **Arm 2:** Lovaza 4g →Epanova 4 g QD • **Arm 3:** Epanova 2g →Lovaza 4g QD • **Arm 4:** Lovaza 4g →Epanova 2g QD Global study – 2 countries	• Plasma concentration vs. time curve (AUC0-τ) [Time Frame: 0 to 24 hours (AUC0-24)]	• FPD: Q3 14 • LPD: Q2 15 • Topline results: Q4 15

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Onglyza (DPP-4 inhibitor)

Type 2 Diabetes

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02104804**	Type 2 diabetes mellitus	N = 444	• **Arm 1**: Onglyza 5 mg QD +insulin or Onglyza 5 mg QD+ insulin + Met: Placebo QD +insulin or Placebo • **Arm 2:** QD + insulin + Met Study in China	Primary: • Change from baseline in HbA1C at 24 weeks Secondary: • Change from baseline at 24 weeks in 120-minute postprandial plasma glucose (PPG) in response to a meal tolerance	• FPD: Q3 14 • LPD: H1 16 • Est. topline results: H1 16
Phase III **NCT02273050**	Type 2 diabetes mellitus	N = 639	• **Arm 1:** *Onglyza* 5 mg + Met (500 mg with titration) • **Arm 2:** *Onglyza* 5 mg + Placebo • **Arm 3:** Met (500 mg with titration) + Placebo Study in China	Primary: • The change in HbA1c from baseline to week 24 (prior to rescue) Secondary • The proportion of subjects achieving a therapeutic glycaemic response at week 24 (prior to rescue) defined as HbA1c <7.0%	• FPD: Q1 15 • LPD: H2 16 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Farxiga/Forxiga (SGLT-2 inhibitor)

Diabetes

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV **NCT02157298**	Japanese patients with type 2 diabetes with inadequate glycemic control on insulin	N = 266	• **Arm 1:** *Forxiga* 5mg • **Arm 2:** Placebo Japan study	• Change from baseline in HbA1c at week 16 • 1 year LT data	• FPD: Q2 14 • LPD: Q4 15 • Topline results: (Short Term part of study) Q3 15 • Est. completion date: H1 16
Phase III/IV **DECLARE** **NCT01730534**	Type 2 diabetes mellitus with high risk for CV event	N = 17,276	• **Arm 1:** Forxiga 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	• FPD: Q2 13 • LPD: 2019 • Est. topline results: 2019 • Est. completion date: 2019
Phase III **NCT02096705** Partnered: BMS	Asian subjects with type 2 diabetes who have inadequate glycemic control on insulin	N = 260	• **Arm 1:** *Forxiga* 10 mg QD for 24 weeks + background Insulin • **Arm 2:** Placebo QD for 24 weeks + background Insulin Asian study 3 countries	• Change from baseline in HbA1c at week 24	• FPD: Q1 14 • LPD: H1 16 • Est. topline results: H1 16 • Est. completion date: H1 16
Phase III **DERIVE** **NCT02413398**	Patients with Type 2 diabetes and moderate renal impairment	N = 302	• **Arm 1:** Forxiga 10 mg QD for 24 weeks • **Arm 2**: Placebo 10 mg QD for 24 weeks Global study – 5 countries	• Change from baseline in HbA1c at Week 24	• FPD: Q2 15 • LPD: 2017 • Est. topline results: 2017 • Est. completion date: 2017
Phase III **DEPICT 1** **NCT02268214** Partnered: BMS	Type 1 diabetes mellitus	N = 768	• **Arm 1:** Forxiga 5 mg QD 52 weeks + insulin • **Arm 2:** Forxiga 10 mg QD 52 weeks + insulin • **Arm 3:** Placebo QD 52 weeks + insulin Global study – 17 countries	Primary: • Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at Week 24	• FPD: Q4 14 • LPD: 2017 • Est. topline results: 2017
Phase III **DEPICT 2** **NCT02460978** Partnered: BMS	Type 1 diabetes mellitus	N = 768	• **Arm 1:** *Forxiga* 5 mg QD 52 weeks + insulin • **Arm 2:** *Forxiga* 10 mg QD 52 weeks + insulin • **Arm 3:** Placebo QD 52 weeks + insulin Global Study-14 countries	Primary: • Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at Week 24	• FPD: Q3 15 • LPD: 2017 • Est. topline results: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

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

Diabetes

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02284893**	Type 2 diabetes mellitus	N = 420	• **Arm 1:** Saxa 5 mg + Dapa 10 mg + Met IR/XR • **Arm 2:** Sitagliptin 100 mg + Met IR/XR Global study – 6 countries	Primary: • Mean change from baseline in HbA1C at week 24 Secondary: • The proportion of subjects achieving a therapeutic glycemic respons at week 24 defined as HbA1C<7% • Mean change in total body weight at week 24	• FPD: Q1 15 • LPD: H1 16 • Est. topline results: H2 16
Phase III **NCT02419612**	Type 2 diabetes mellitus	N = 440	• **Arm 1:** Saxa 5 mg + Dapa 10 mg + Met IR/XR • **Arm 2:** Glimeperide 1-6 mg + Met IR/XR Global study – 10 countries	Primary: • Mean change from baseline in HbA1c at week 52 Secondary: • Mean change from baseline in total body weight at Week 52 • The proportion of subjects achieving a therapeutic glycemic response at week 52 defined as HbA1c<7.0%,	• FPD: Q3 15 • LPD: H2 16 • Est. topline results: 2017
Phase III **NCT02551874**	Type 2 diabetes mellitus	N = 598	• **Arm 1:** Saxa 5 mg + Dapa 10 mg + Met IR/XR with or without SU • **Arm 2:** Glargine insulin + Met IR/XR with or without SU Global study – 12 countries	Primary: • Mean change from baseline in HbA1C at week 24 Secondary: • Mean change in total body weight at week 24 • The proportion of subjects with confirmed hypoglycemia at week 24	• FPD: Q4 15 • LPD: H2 16 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Bydureon (GLP-1 receptor agonist)

Type 2 Diabetes

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IV **EXSCEL** **NCT01144338** Partnered	Type 2 diabetes	N = 14,000	• **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)	• FPD: Q2 10 • LPD: 2017 • Est. completion: 2018
Phase III **DURATION-NEO 1** **NCT01652716** Partnered	Type 2 diabetes	N = 375	• **Arm 1:** *Bydureon* BiD SC (autoinjector) • **Arm 2:** *Bydureon* weekly suspension SC (autoinjector) On a background of diet & exercise alone or with stable regimen of oral antidiabetes US only	• Change in HbA1c from baseline at 28 weeks	• FPD: Q1 13 • Completed: Q3 14
Phase III **DURATION-NEO 2** **NCT01652729** Partnered	Type 2 diabetes	N = 360	• **Arm 1:** Sitagliptin • **Arm 2:** *Bydureon* weekly suspension SC (autoinjector) • **Arm 3:** Placebo On a background of diet & exercise alone or with stable regimen of oral antidiabetes US only	• Change in HbA1c from baseline at 28 weeks	• FPD: Q1 13 • Completed : Q3 14
Phase III **DURATION 7** **NCT02229383**	Type 2 diabetes	N = 440	• **Arm 1:** *Bydureon* once weekly 2 mg SC + Titrated Basal Insulin • **Arm 2:** Placebo + Titrated Basal Insulin Double-blind 1:1 randomisation Background therapy with or without Metformin Global Study	• Change in HbA1c from baseline at 28 weeks	• FPD: Q3 14 • LPD: H2 16 • Est. completion: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Bydureon (GLP-1 receptor agonist)

Type 2 Diabetes

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **DURATION 8** **NCT02229396**	Type 2 diabetes	N = 660	• **Arm 1:** *Bydureon* once weekly 2 mg SC • **Arm 2:** Dapagliflozin 10 mg • **Arm 3:** *Bydureon* once weekly 2 mg SC + Dapagliflozin 10 mg Double-blind 1:1:1 randomisation Background therapy with Metformin 1500 mg/day up to 2 months prior to screening Global Study	• Change in HbA1c from baseline at 28 weeks	• FPD: Q3 14 • LPD: 2017 • Est. completion: • H2 16 - 28-week data • 2017 - 52-week data • 2018 - 104-week data

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Faslodex (oestrogen receptor antagonist)

Breast cancer - metastatic

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **FALCON** **NCT01602380**	Postmenopausal women with HR+ locally advanced or metastatic breast cancer, who have not previously been treated with any hormonal therapy (1^{st}-line)	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	• FPD: Q4 12 • LPD: Q3 14 • Est. topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Lynparza (PARP inhibitor)

Ovarian cancer and other solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **SOLO-2** **Partnered** **NCT01874353**	PSR BRCAm ovarian cancer	N = 264	• **Arm 1:** *Lynparza* tablets 300 mg BiD as maintenance therapy until progression • **Arm 2:** placebo tablets BiD Global study	• Progression Free Survival • Overall Survival secondary endpoint	• FPD: Q3 13 • LPD: Q4 14 • Est. topline results: H2 16
Phase III **SOLO-1** **Partnered** **NCT01844986**	1L maintenance BRCAm ovarian cancer	N = 344	• **Arm 1:** *Lynparza* tablets 300 mg BiD maintenance therapy for 2 years or until disease progression • **Arm 2:** placebo Global study	• Progression Free Survival • Overall Survival secondary endpoint	• FPD: Q3 13 • LPD: Q1 15 • Est. topline results: 2017
Phase III **SOLO-3** **NCT02282020**	PSR gBRCAm ovarian cancer 3+ Line	N = 411	• **Arm 1:** *Lynparza* 300 mg BiD to progression • **Arm 2:** Physician's choice (single agent chemotherapy) Global study	• Progression Free Survival • Overall Survival secondary endpoint	• FPD: Q1 15 • LPD: 2017 • Est. topline results: 2018
Phase III **GOLD** **NCT01924533**	2L gastric cancer (all patients with a co-primary sub population)	N = 525	• **Arm 1:** paclitaxel + *Lynparza* until progression • **Arm 2:** paclitaxel + placebo *Lynparza* dose 100mg BiD throughout paclitaxel dose cycle & 300 mg BiD post cycle Asian study	• Overall Survival	• FPD: Q3 13 • LPD: Q4 15 • Est. topline results: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Lynparza (PARP inhibitor)

Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **OlympiAD** **NCT02000622**	BRCAm metastatic breast cancer	N = 310	• **Arm 1:** Lynparza 300 mg BiD, continuous to progression • **Arm 2:** Physician's choice: Capecitabine 2500 mg/m2 x 14 q 21 Vinorelbine 30 mg/m2 d 1, 8 q 21 Eribulin 1.4 mg/m2 d 1, 8 q 21 to progression Global study	• Progression Free Survival • Secondary endpoint: Overall Survival	• FPD: Q2 14 • LPD: Q4 15 • Est. topline results: H2 16
Phase III **OlympiA** **Partnered** **NCT02032823**	BRCAm adjuvant breast cancer	N = 1,500	• **Arm 1:** Lynparza 300 mg BiD 12 month duration • **Arm 2:** Placebo 12 month duration Global study partnership with BIG and NCI/NRG	• Invasive Disease Free Survival (IDFS) • Secondary endpoint: Distant Disease Free Survival and Overall Survival	• FPD: Q2 14 • LPD: 2018 • Est. topline results: 2020
Phase III **POLO** **NCT02184195**	Pancreas gBRCA	N = 145	• **Arm 1:** Lynparza tablets 300 mg twice daily as maintenance therapy until progression. • **Arm 2:** placebo tablets BiD Global study	• Primary endpoint: Progression Free Survival • Secondary endpoint: Overall Survival	• FPD: Q1 15 • LPD: 2017 • Est. topline results: 2018
Phase II **NCT01972217**	Metastatic castration resistant prostate CA	N = 140	• **Arm 1:** Lynparza 300mg BiD + Abiraterone • **Arm 2:** Placebo + Abiraterone Global study	• Radiologic Progression Free Survival	• FPD: Q3 14 • LPD: Q3 15 • Est. topline results: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Tagrisso (Highly selective, irreversible EGFR TKI)

Non-small cell lung cancer (NSCLC)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **AURA3** **NCT02151981**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	N = 410	• **Arm 1:** AZD9291 80mg QD • **Arm 2:** pemetrexed 500mg/m2 + carboplatin AUC5 or pemetrexed 500mg/m2 + cisplatin 75mg/m2 (2:1 randomisation Global study	• Progression Free Survival • Overall Survival is a secondary endpoint • PFS • OS and QoL as secondary endpoints	• FPD: Q3 14 • Enrollment complete • Est. primary completion: H2 16
Phase III **FLAURA** **NCT02296125**	Advanced EGFRm NSCLC 1L	N = 650	• **Arm 1:** AZD9291 80mg • **Arm 2:** erlotinib 150mg or gefitinib 250 mg (dealers choice); 1:1 randomisation Global study	• PFS • OS and QoL as secondary endpoints	• FPD: Q1 15 • Est. completion: 2017
Phase III **ADAURA** **NCT02511106**	Adjuvant EGFRm NSCLC	N = 700	• **Arm 1:** AZD9291 80mg QD following complete tumour resection, with or without chemotherapy • **Arm 2:** placebo Global study	• DFS • DFS Rate, OS, OS Rate, QoL	• FPD: Q4 15 • Est. completion: 2022
Phase III **CAURAL** **NCT02454933**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	N = 350	• **Arm 1:** AZD9291 (80mg QD) + MEDI4736 1(0mg/kg q2w (IV) infusion) • **Arm 2:** AZD9291 (80mg QD) Global study	• PFS • ORR, OS, QoL as secondary endpoints	• FPD: Q3 15 • Partial hold • Est. completion: 2018
Phase II **AURA17** **NCT02442349**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	N = 175	• AZD9291 80 mg QD Asia Pacific Regional Study	• ORR • PFS and OS secondary endpoints	• FPD: Q3 15 • Enrollment complete • Est. primary completion: H1 16
Phase II **AURA2** **NCT02094261**	Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	N = 175	• AZD9291 80 mg QD Global study	• ORR • PFS and OS secondary endpoints	• FPD: Q2 14 • Enrollment complete (N=210)
Phase I/II **AURA** **NCT01802632**	Advanced EGFRm NSCLC TKI failure + /- primary resistance mutation T790M	N ~ 500	• Dose escalation study • Ph II Extension cohort (T790M only) 80mg QD Global study	• Safety and tolerability • ORR • PFS and OS secondary endpoints	• FPD: Q1 13 • Enrollment complete (N=201 in extension portion)

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Tagrisso (Highly selective, irreversible EGFR TKI)

Non-small cell lung cancer (NSCLC)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib **TATTON** **NCT02143466**	Advanced EGFRm NSCLC TKI failure	N ~ 90	• **Arm 1:** AZD9291 + MEDI4736 • **Arm 2:** AZD9291 + AZD6094 • **Arm 3:** AZD9291 + selumetinib Global study	• Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity	• FPD: Q3 14 • Dose escalation completed • Dose expansions ongoing • Partial hold on durvalumab combo arms
Phase I **BLOOM** **NCT02228369**	EGFRm NSCLC, CNS disease	N = 47	• MAD • Expansion in LM patients at RP2D with AZD3759 • Expansion in LM patients at 160mg with AZD9291 Global study, 4 countries	• Safety and tolerability • Preliminary anti-tumour activity	• FPD: Q4 14 • Est. completion: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Nexium

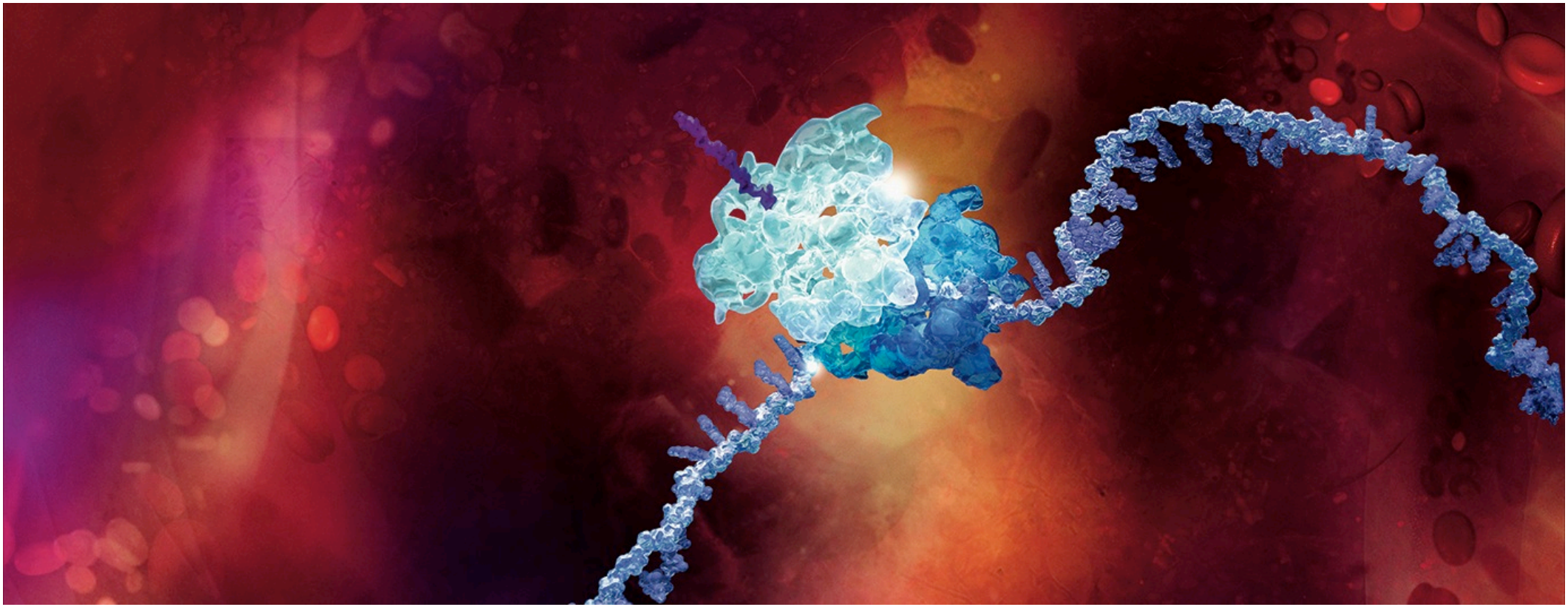
Gastrointestinal

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02157376**	Seriously ill patients with at least one major risk factor for stress ulcer related bleeding (Stress Ulcer Prophylaxis, SUP)	N = 300	• **Arm 1:** *Nexium* 40 mg bid intermittent iv infusions given for max. 14 days • **Arm 2:** Cimetidine(Tagamet) 300 mg bolus iv infusion followed by continuous iv infusion 50mg/h for max. 14 days China-only study	• Clinically significant upper GI bleeding	• FPD: Q3 14 • LPD: H1 16 • Est. completion: H1 16

AstraZeneca

AstraZeneca
What science can do

Late-stage development



Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

PT003 (LABA/LAMA)

COPD

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **PINNACLE 1** **NCT01854645**	Moderate to very severe COPD	N = 2,103	Treatment (24-week Treatment Period) • **Arm 1:** GFF MDI (PT003) 14.4/9.6 µg BiD • **Arm 2:** GP MDI (PT001) 14.4 µg BiD • **Arm 3:** FF MDI (PT005) 9.6 µg BiD • **Arm 4:** Open-label tiotropium bromide inhalation powder 18 µg QD • **Arm 5:** Placebo MDI BiD Multicenter, randomized, double-blind, parallel-group, chronic dosing, placebo- and active- controlled Estimated time from FSFV to DBL is approximately 21 months. US, Australia, New Zealand	• Change from baseline in morning pre-dose trough FEV_1	• FPD: Q2 13 • LPD: Q3 14 • Topline results: Q1 15* * Clinically completed
Phase III **PINNACLE 2** **NCT01854658**	Moderate to very severe COPD	N = 1,618	Treatment (24-week Treatment Period) • **Arm 1:** GFF MDI (PT003) 14.4/9.6 µg BiD • **Arm 2:** GP MDI (PT001) 14.4 µg BiD • **Arm 3:** FF MDI (PT005) 9.6 µg BiD • **Arm 4:** Placebo MDI BiD Multicenter, randomized, double-blind, parallel group, chronic dosing and placebo-controlled Estimated time from FSFV to DBL is approximately 20 months. US	• Change from baseline in morning pre-dose trough FEV	• FPD: Q3 13 • LPD: Q3 14 • Topline results: Q2 15* * Clinically completed
Phase III **PINNACLE 3** **NCT01970878**	Moderate to very severe COPD	N = 850	Treatment (28-week Treatment Period) • **Arm 1:** GFF MDI (PT003) 14.4/9.6 µg BiD • **Arm 2:** GP MDI (PT001) 14.4 µg BiD • **Arm 3:** FF MDI (PT005) 9.6 µg BiD • **Arm 4:** Open-label tiotropium bromide inhalation powder QD Multi-center, randomized, double-blind, parallel-group and active-controlled Estimated time from FSFV to DBL is approximately 16 months. US, Australia, New Zealand	• Overall safety, tolerability and efficacy	• FPD: Q4 13 • LPD: Q3 14 • Topline results: Q2 15* * Clinically completed

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

PT003 (LABA/LAMA)

COPD

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIIb (Dose Indicator Study) **NCT02268396**	Moderate to severe COPD	N = 150	Treatment (5- to 6- week Treatment Period) • GFF 14.4/9.6 µg • Placebo MDI BID Open-label and multiple-centre Estimated time from FSFV to DBL is approximately 11 weeks. US	• Percentage of devices where number of actuations as counted at the end of the study using dose indicator reading is consistent (± 20 actuations) with number of actuations reported by subject	• FPD: Q4 14 • LPD: Q4 14 • Topline results: Q1 15* * Clinically completed
Phase IIIb (24 Hr Lung Function Placebo) **NCT02347085**	Moderate to severe COPD	N = 40	Treatments (8-week Treatment Period) • GFF MDI 14.4/9.6 µg BID • Placebo MDI BID Randomized, 2-period, 2-treatment Double-blind, Multi-centre and Crossover Estimated time from FSFV to DBL is approximately 7 months, US	• FEV1 AUC0-24 on Day 29	• FPD: Q1 15 • LPD: Q1 15 • Est. topline results: Q3 15 * Clinically completed
Phase IIIb (24 Hr Lung Function Active) **NCT02347072**	Moderate to severe COPD	N = 80	Treatments (12-week Treatment Period) • GFF MDI 14.4/9.6 µg BID • Placebo • Spiriva Respimat 5 µg QD (open-label) Randomized and 3-way cross-over Estimated time from FSFV to DBL is approximately 10 months, US	• FEV1 AUC0-24 on Day 29	• FPD: Q1 15 • LPD: Q2 15 • Est. topline results: Q3 15 * Clinically completed
Phase III (Spacer Study) **NCT02454959**	Moderate to severe COPD	N = 60	Treatments (2 week treatment Period) • GFF MDI 14.4/9.6 µg with a spacer • GFF MDI 14.4/9.6 µg without a spacer Randomized, 7-day, cross-over in subjects with moderate to severe COPD Estimated time from FSFV to DBL is approximately 10 weeks. US	• Change from morning pre-dose trough FEV_1 GFF 14.4/9.6 µg with Aerochamber Plus VHC relative to GFF14.4µg w/o Aerochamber Plus VHC on Day 8 • PK parameters at all doses will include Cmax, AUC0-12, AUC0-t, tmax, Other PD/PK parameters may be calculated, as appropriate	• FPD: Q2 15 • LPD: H1 16 • Est. topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

PT003 (LABA/LAMA)

COPD

Study phase	Patient population	Number of patients	Design (G = Glycopyrronium, F = Formoterol fumarate)	Endpoints	Status
Phase III **(Asia Pacific study)** **NCT02343458**	Moderate to very severe COPD	N = 1,614	Treatments (24-week Treatment Period) • GFF 14.4/9.6 µg (N=514) • GP 14.4 µg (N=440) • FF 9.6 µg (N=440) • Placebo (N=220) • US/China: Trough FEV1 at Week 24 of treatment • EU/Hybrid: Co-primary= Trough FEV1 over Week 24 of treatment and TDI score over 24 weeks Randomized, Double-Blind, Chronic-Dosing , Placebo-Controlled, Parallel-Group and Multi-centre Estimated time from FSFV to DBL is approximately 20 months. US, UK, Germany, Costa Rica, Hungary, Poland, Russia, South Korea, Taiwan, China, Japan	• For the US/China approach, the primary endpoint will be the change from baseline in morning pre-dose trough FEV1 at Week 24 of treatment • For the Japan approach, the primary endpoint will be the change from baseline in morning pre-dose trough FEV1 over Weeks 12 to 24 of treatment • For the EU and Hybrid approaches, the primary endpoint will be the change from baseline in morning pre-dose trough FEV1 over 24 weeks of treatment • TDI score (co-primary endpoint for EU and Hybrid) [Time Frame: Over 24 Weeks]	• FPD: Q2 15 • LPD: H1 16 • Est. topline results: 2017
Phase IIb **(CV study)**	Moderate to sever COPD	N = 32	Treatments (5-week Treatment Period) • GFF MDI (PT003) 14.4/9.6 µg ex-actuator • Placebo MDI Randomized, 2-period, Double-blind, 2-treatment, Chronic-dosing (7 Days), Crossover Study Estimated time from FSFV to DB is approximately 8 months, US	• Right Ventricular End Diastolic Volume Index (RVEDVi) measured at 2-hours post-dose on Day 8	• FPD: H1 16 • LPD: H2 16 • Est. topline results: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

PT009 (ICS/LABA)

COPD & Asthma

Study phase	Patient population	Number of patients	Design (G = Glycopyrronium, F = Formoterol fumarate)	Endpoints	Status
Phase II **(BFF Dose-ranging)** **NCT02196077**	Moderate to severe COPD	N = 180	• BFF MDI 320/9.6 µg BiD • BFF MDI 160/9.6 µg BiD • BFF MDI 80/9.6 µg BiD • BD MDI 320 µg BiD • FF MDI 9.6 µg BiD Randomized, 4-period, 5-treatment incomplete-block and crossover Estimated time from FSFV to DBL is approximately 7 months. US	• Forced expiratory volume in 1 second area under the curve from 0 to 12 hours (FEV_1 AUC_{0-12})	• FPD: Q3 14 • LPD: Q3 14 • Topline results: Q2 15* * Clinically completed

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

PT010 (LABA/LAMA/ICS)
COPD & Asthma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **(Long-term BMD and Ocular Safety)** **NCT02536508**	Moderate to very severe COPD	N = 500	Treatments (52-week Treatment Period) • BGF MDI 320/14.4/9.6 µg • GFF MDI 14.4/9.6 µg • BFF MDI 320/9.6 µg • Symb TBH 400/12 µg Estimated time from FSFV to DBL TBD, Country US Study design to be confirmed	Bone Mineral Density Sub-study Endpoint: • Change from baseline in BMD of the lumbar spine measured using DXA scans of L1-L4 at Week 52 Ocular Sub-study Safety Endpoint: • Change from baseline in LOCS III at Week 52	• FSD: Q3 15 • LPD: H2 16 • Est. topline results: 2017
Phase III **(Exacerbation study)** **ETHOS** **NCT02465567**	Moderate to very severe COPD	N = 10,000	Treatments (1-year Treatment Period) • BGF MDI 320/14.4/9.6 µg • BGF MDI 160/14.4/9.6 µg • BFF MDI 320/9.6 µg • GFF MDL 14.4/9.6 µg Randomized, double-blind, multi-centre and parallel-group Estimated time from FSFV to DBL is approximately 3 years. Multi-country	• Rate of moderate or severe COPD exacerbations • Time to first moderate or severe COPD exacerbation	• FPD: Q3 15 • LPD: 2017 • Est. topline results: 2018
Phase III **(Lung function study)** **KRONOS** **NCT02497001**	Moderate to very severe COPD	N = 1,800	Treatments (24-week Treatment Period) • BGF MDI 320/14.4/9.6 µg • GFF MDI 14.4/9.6 µg • BFF MDI 320/9.6 µg • Symb TBH 400/12 µg Randomized, double-blind, parallel-group, and chronic dosing and multi-centre Estimated time from FSFV to DBL is approximately 2 years. Multi-country	Co-Primary Endpoints (EU): • FEV1 area under curve from 0 to 4 hours (AUC0-4) over 24 weeks (BGF MDI vs BFF MDI and BGF MDI vs Symbicort TBH) • Change from baseline in morning pre-dose trough FEV1 over 24 weeks (BGF MDI vs GFF MDI) • Transition dyspnea index (TDI) focal score over 24 weeks (BGF MDI vs BFF MDI and BGF MDI vs GFF MDI) Primary Endpoint (Japan): • Change from baseline in morning pre-dose trough FEV1 over 24 weeks (BGF MDI vs BFF MDI, BGF MDI vs GFF MDI) Primary Endpoint (US): • FEV1 area under curve from 0 to 4 hours (AUC0-4) at Week 24 (BGF MDI vs BFF MDI • Change from baseline in morning pre-dose trough FEV1 at Week 24 (MDI vs GFF MDI)	• FPD: Q3 15 • LPD: 2017 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

PT010 (LABA/LAMA/ICS)

COPD & Asthma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II (BD Dose-ranging in Asthma) **NCT02105012**	Adult mild to moderate persistent asthma	N = 150	• **Arm 1:** BD MDI 320 µg BiD • **Arm 2:** BD MDI 160 µg BiD • **Arm 3:** BD MDI 80 µg BiD • **Arm 4:** BD MDI 40 µg BiD • **Arm 5:** Placebo MDI BiD Randomized, 4-period, 5-treatment incomplete-block and crossover 4 week Estimated time from FSFV to DBL is approximately 18 months. US	• Change from baseline in morning pre-dose trough forced expiratory volume in one second (FEV1)	• FPD: Q2 14 • LPD: Q1 15 • Topline results: Q3 15 * Clinically completed
Phase II **NCT02433834**	Intermittent asthma/mild to moderate persistent asthma	N = 200	Treatment (18-week Treatment Period) • GP MDI 28.8 µg BiD • GP MDI 14.4 µg BiD • GP MDI 7.2 µ BID • GP MDI 3.6 µ BID • Severent® Diskus® 50µ BID • Placebo MDI Randomized, double-blind, chronic-dosing, placebo controlled, incomplete block, cross over, multi-centre, dose-ranging study Estimated time from FSFV to DBL is approximately 11 months. US	• Peak change from baseline in FEV1 within 3 hours post-dosing on Day 15	• FPD: Q2 15 • LPD: Q4 15 • Topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

PT010 (LABA/LAMA/ICS)

COPD & Asthma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **(BGF PK study)** **NCT02189304**	Healthy volunteers	N = 72	• **Arm 1:** BGF MDI 320/14.4/9.6 µg • **Arm 2:** BFF MDI (320/9.6 µg) • **Arm 3:** Symbicort Turbuhaler® 400/12 µg Randomized, double-blind, single-dose, 3-period, 3-treatment and crossover Estimated time from FSFV to DBL is approximately 3 months. US	• Overall safety • PK parameters $AUC_{0\text{-}12}$ and Cmax	• FPD: Q3 14 • LPD: Q3 14 • Topline results: Q4 14* * Clinically completed
Phase I **(BGF PK in Japanese Subjects)** **NCT02197975**	Japanese healthy volunteers	N = 20	Treatment (2-week Treatment Period) • **Arm 1:** BGF MDI 320/14.4/9.6 µg • **Arm 2:** BGF MDI 160/14.4/9.6 µg • **Arm 3:** Placebo MDI Randomized, double-blind, placebo-controlled, 2-period, ascending-dose and crossover Estimated time from FSFV to DBL is approximately 8 weeks. Japan	• Overall safety • PK parameters $AUC_{0\text{-}12}$ and Cmax	• FPD: Q3 14 • LPD: Q3 14 • Topline results: Q4 14* * Clinically completed
Phase I **(GFF PK in Japanese Subjects)** **NCT02196714**	Japanese healthy volunteers	N = 24	Treatment (4-day Treatment Period) • **Arm 1:** GFF MDI 14.4/9.6 µg • **Arm 2:** GFF MDI 28.8/9.6 µg • **Arm 2:** GP MDI 14.4 µg • **Arm 2:** GP MDI 28.8 µg Randomized, double-blind, single-dose, 4-Period, 4-treatment and crossover Estimated time from FSFV to DBL is approximately 13 weeks. Japan	• Overall safety • PK parameters $AUC_{0\text{-}12}$ and Cmax	• FPD: Q3 14 • LPD: Q3 14 • Topline results: Q4 14* * Clinically completed

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Benralizumab (IL-5Rα mAb)

Asthma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **CALIMA** **NCT01914757**	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12 – 75yrs	N = 1,026 HD + ~200 MD	• **Arm 1:** 30 mg Q8w SC • **Arm 2:** 30 mg Q4w SC • **Arm 3:** Placebo SC 56-week 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	• FPD: Q4 13 • Est. completion: H2 16
Phase III **SIROCCO** **NCT01928771**	Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA ± chronic OCS Age 12 – 75 yrs	N = 1,134	• **Arm 1:** 30 mg Q8w SC • **Arm 2:** 30 mg Q4w SC • **Arm 3:** Placebo SC 48-week 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	• FPD: Q4 13 • Est. completion: H2 16
Phase III **ZONDA** **NCT02075255**	Severe asthma, inadequately controlled on HD ICS plus long-acting β2 agonist and chronic oral corticosteroid therapy Age 18 – 75 yrs	N = 210	• **Arm 1:** 30 mg Q8w SC • **Arm 2:** 30 mg Q4w SC • **Arm 3:** Placebo SC 46-week study Global study – 12 countries	• Reduction of oral corticosteroid dose	• FPD: Q3 14 • Est. completion: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Benralizumab (IL-5Rα mAb)

Asthma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **BISE** **NCT02322775**	Asthmatic with FEV1 (50-90% predicted) on low to medium dose inhaled corticosteroid Age 18 – 75 yrs	N = 200	• **Arm 1:** 30 mg Q4w SC • **Arm 3:** Placebo SC 12-week study Global study – 6 countries	• Pulmonary function (FEV1)	• FPD: Q1 15 • Est. completion: H1 16
Phase III **BORA** **NCT02258542**	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 12 – 75yrs	N = 2,550	• **Arm 1:** 30 mg Q4w SC • **Arm 2:** 30 mg Q8w SC* * Placebo administered at select interim visits to maintain blind between treatment arms 56-week (adults) 108-week (adolescents) Global study	• Safety and tolerability	• FPD: Q4 14 • Est. completion: 2018
Phase III **GREGALE** **NCT02417961**	Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA ± chronic OCS Age 18 – 75yrs	N = 120	• **Arm 1:** 30 mg Q4w SC 28-week (adults) Global study – 2 countries	• Functionality, Reliability, and Performance of a Pre-filled Syringe With Benralizumab Administered at Home	• FPD: Q2 15 • Est. completion: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Benralizumab (IL-5Rα mAb)

COPD

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **TERRANOVA** **NCT02155660**	Moderate to very severe Chronic Obstructive Pulmonary Disease (COPD) with exacerbation history	N = 2,168	• **Arm 1:** 10 mg Q8w SC • **Arm 2:** 30 mg Q4w SC • **Arm 3:** 100 mg Q8w SC • **Arm 4:** Placebo SC 48-week study Global study – 23 countries	• Rate of COPD exacerbation	• FPD: Q3 14 • Est. completion: 2018
Phase III **GALATHEA** **NCT02138916**	Moderate to very severe Chronic Obstructive Pulmonary Disease (COPD) with exacerbation history	N = 1,626	• **Arm 1:** 30 mg Q4w SC • **Arm 2:** 100 mg Q8w SC • **Arm 3:** Placebo SC 48-week study Global study –17 countries	• Rate of COPD exacerbation	• FPD: Q3 14 • Est. completion: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Tralokinumab (IL-13 mAb)

Asthma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **STRATOS 1** **NCT02161757**	Adults with uncontrolled severe asthma	N = 1,140	Cohort 1: • **Arm 1:** Tralokinumab dose regimen 1, SC • **Arm 2:** Placebo SC Cohort 2 : • **Arm 1:** Tralokinumab dose regimen 2, SC • **Arm 2:** Placebo SC 2:1 randomisation in both cohorts Global study – 15 countries	Primary: • Asthma exacerbation rate reduction Key Secondary: • Effect of tralokinumab on measures of pulmonary function (FEV1), asthma symptoms (Asthma Daily Diary), asthma control (ACQ-6) and asthma related QoL (AQLQ (S) +12)	• FPD: Q3 14 • LPD: H1 16 • Est. completion date: 2017 • Est. topline results: 2017
Phase III **STRATOS 2** **NCT02194699**	Adults with uncontrolled severe asthma	N = 770	• **Arm 1:** Tralokinumab SC • **Arm 2:** Placebo SC 1:1 randomisation Global study – 13 countries including Japan	Primary: • Asthma exacerbation rate reduction Key Secondary: • Effect of tralokinumab on measures of pulmonary function (FEV1), asthma symptoms (Asthma Daily Diary), asthma control (ACQ-6) and asthma related QoL (AQLQ (S) +12)	• FPD: Q1 15 • LPD: H2 16 • Est. completion date: 2017 • Est. topline results: 2017
Phase III **TROPOS** **NCT02281357**	Adults with oral corticosteroid dependent asthma	N = 120	• **Arm 1:** Tralokinumab SC • **Arm 2:** Placebo SC 1:1 randomisation Global studies - 6 countries	Primary: • % Change in OCS dose Key Secondary: • Proportion of subjects achieving final daily OCS dose ≤5 mg • Proportion of subjects achieving ≥50% reduction in OCS dose	• FPD: Q1 15 • LPD: H2 16 • Est. completion date: 2017 • Est. topline results: 2017
Phase II **MESOS** **NCT02449473**	Adults with uncontrolled asthma	N = 80	• **Arm 1:** Tralokinumab SC • **Arm 2:** Placebo SC 1:1 randomisation 3 countries	Primary: • Change in number of airway submucosal eosinophils Secondary: • Change in blood eosinophils levels • Change in eosinophil cationic protein as a measure of activated eosinophils in blood and sputum	• FPD: Q3 15 • LPD: 2017 • Est. completion date: 2018 • Est. topline results: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Tralokinumab (IL-13 mAb)

Idiopathic Pulmonary Fibrosis (IPF)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01629667**	Adults with Idiopathic Pulmonary Fibrosis	N = 176	• **Arm 1:** Tralokinumab high dose 800mg IV • **Arm 2:** Tralokinumab low dose 400mg IV • **Arm 3:** Placebo IV High dose: low dose: placebo (1:1:1) Global study – 6 countries	• Change from baseline in percent-predicted forced vital capacity at week 52* Key Secondary Endpoints: • No. of patients with disease progression • Safety and tolerability • Tralokinumab serum concentration	• FPD: Q4 12 • LPD: Q1 15 • Interim analysis: Q3 15 • Terminated
Phase II **NCT02036580**	Japanese adults with Idiopathic Pulmonary Fibrosis	N = 20	Cohort 1: • **Arm 1:** Tralokinumab Low dose 400mg IV • **Arm 2:** Placebo IV Cohort 2 : • **Arm 1:** Tralokinumab High dose 800mgIV • **Arm 2:** Placebo IV 8:2 randomisation in both cohorts Japan only study	• Safety and tolerability Key Secondary Endpoints: • Tralokinumab serum concentration • Immunogenicity	• FPD: Q1 14 • LPD: Q4 14 • Completion date: Q4 15 • Terminated

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Tralokinumab (IL-13 mAb)

Atopic dermatitis

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02347176**	Adults with atopic dermatitis	N = 204	• **Arm 1:** Tralokinumab dose 45mg SC • **Arm 2:** Tralokinumab dose 150mg SC • **Arm 3:** Tralokinumab dose 300mg SC • **Arm 4**: Placebo SC Global study – 6 countries	• Change from baseline in SCORAD at week 12 Key Secondary Endpoints: • Percentage of subjects achieving IGA of 0 or 1 • Change from baseline in EASI • Percentage of subjects achieving EASI50 and SCORAD50 • Change from baseline in puritis • Safety and tolerability • Tralokinumab serum concentration	• FPD: Q1 15 • LPD: Q4 15 • Est. completion date: H1 16 • Est. topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Anifrolumab (type I IFN receptor mAb)

Systemic Lupus Erythematosus (SLE)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **NCT02446912**	Moderate to severe Systemic Lupus Erythematosus (SLE) TULIP SLE 1	N = 450	• **Arm 1:** 300 mg IV MEDI-546 Q4W for 48 weeks • **Arm 2:** 150 mg IV MEDI-546 Q4W for 48 weeks • **Arm 3:** placebo IV Q4W for 48 weeks	Response in SLE responder index at week 52	• FPD: Q3 15 • LPD: 2018 • Est. topline results: 2018
Phase III **NCT02446899**	Moderate to severe Systemic Lupus Erythematosus (SLE) TULIP SLE 2	N = 360	• **Arm 1:** 300 mg IV MEDI-546 Q4W for 48 weeks • **Arm 2:** 150 mg IV MEDI-546 Q4W for 48 weeks	Response in SLE responder index at week 52	• FPD: Q3 15 • LPD: 2018 • Est. topline results: 2018
Phase II **NCT01438489**	Moderate to severe SLE patients	N = 307 (final)	• **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	• FPD: Q1 12 • Topline results: Q3 14
Phase II **NCT01753193**	Moderate to severe SLE patients	N = 218	• **Arm 1:** MEDI-546, IV Q4W for 104 weeks	Open-label extension to evaluate long-term safety and tolerability	• FPD: Q1 13 • Est. topline results: 2017
Phase II **NCT01559090**	Japanese SLE patients	N = 17	Open-label, dose escalation study: • **Arm 1:** 100mg IV q4 weeks for 48 weeks then 300mg IV q4wks for 104 weeks • **Arm 2:** 300mg IV q4 weeks for 48 weeks then 300mg IV q4wks for 104 weeks • **Arm 3:** 1000mg IV q4 weeks for 48 weeks then 1000mg IV q4wks for 104 weeks	Safety, tolerability, PK/PD	• Topline results: Q1 15
Phase I **NCT02601625**	Healthy volunteers	N= 30	• Arm 1: 300mg SC single dose • Arm 2: 300mg IV single dose • Arm 3: 600 mg SC single dose	Safety, tolerability, PK/PD	• FPD: Q4 15 • LPD: H1 16 • Est. topline results: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Anifrolumab (type I IFN receptor mAb)

Lupus Nephritis (LN)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02547922**	Active Proliferative Lupus Nephritis (TULIP-LN1)	N = 150	• **Arm 1:** 900 mg IV Q4W for 12 weeks then 300 mg IV MEDI-546 Q4W for 36 weeks • **Arm 2:** 300 mg IV MEDI-546 Q4W for 48 weeks • **Arm 3:** placebo IV Q4W for 48 weeks	Response in proteinuria at week 52	• FPD: Q4 15 • LPD: 2018 • Est. topline results: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Brodalumab (IL-17R mAb)

Psoriasis

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **AMAGINE-1** **NCT01708590**	Moderate to severe plaque psoriasis	N = 661	• **Arm 1:** 210 mg brodalumab SC • **Arm 2:** 140 mg brodalumab SC • **Arm 3:** placebo SC	• PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12	• Completed - Partnered
Phase III **AMAGINE-2** **NCT01708603**	Moderate to severe plaque psoriasis	N = 1,800	• **Arm 1:** 210 mg brodalumab SC • **Arm 2:** 140 mg brodalumab SC • **Arm 3:** 45 or 90 mg ustekinumab SC • **Arm 4:** placebo SC	• PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12	• Completed - Partnered
Phase III **AMAGINE-3** **NCT01708629**	Moderate to severe plaque psoriasis	N = 1,881	• **Arm 1:** 210 mg brodalumab SC • **Arm 2:** 140 mg brodalumab SC • **Arm 3:** 45 or 90 mg ustekinumab SC • **Arm 4:** placeboSC	• PASI at wk 12 • Static physician's global assessment (sPGA) at wk 12	• Completed - Partnered

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Roxadustat (HIF-PHI)

Chronic Kidney Disease (CKD)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III ANDES **NCT01750190**	Anaemia in Chronic Kidney Disease patients not receiving dialysis	N = 600	• **Arm 1:** Roxadustat • **Arm 2:** Placebo Global study – 15 countries	Haemoglobin response	• FPD: Q4 12 • Est. completion: 2017 Sponsored by FibroGen
Phase III ALPS **NCT01887600**		N = 600	• **Arm 1:** Roxadustat • **Arm 2:** Placebo Global study – 16 countries	Haemoglobin response	• FPD: Q2 13 • Est. completion: H1 16 Sponsored by Astellas
Phase III DOLOMITES **NCT02021318**		N = 570	• **Arm 1:** Roxadustat • **Arm 2:** Darbepoetin alfa Global study –17 countries	Haemoglobin response	• FPD: Q1 14 • Est. completion: 2017 Sponsored by Astellas
Phase III OLYMPUS **NCT02174627**		N = 2,600	• **Arm 1:** Roxadustat • **Arm 2:** Placebo Global study – 24 countries	MACE	• FPD: Q3 14 • Est completion: 2017 Sponsored by AstraZeneca
Phase III ROCKIES **NCT02174731**	Anaemia in CKD in patients receiving dialysis	N = 1,425	• **Arm 1:** Roxadustat • **Arm 2:** Epoetin alfa Global study – 18 countries	MACE	• FPD: Q3 14 • Est completion: 2017 Sponsored by AstraZeneca
Phase III SIERRAS **NCT02273726**		N = 600	• **Arm 1:** Roxadustat • **Arm 2:** Epoetin alfa Global study – 1 country	Haemoglobin response	• FPD: Q4 14 • Est. completion: 2017 Sponsored by FibroGen
Phase III PYRENEES **NCT02278341**		N = 750	• **Arm 1:** Roxadustat • **Arm 2:** Erythropoiesis Stimulating Agent Global study –19 countries	Haemoglobin response	• FPD: Q4 14 • Est. completion: 2017 Sponsored by Astellas
Phase III HIMALAYAS **NCT02052310**	Anaemia in newly initiated dialysis patients	N = 750	• **Arm 1:** Roxadustat • **Arm 2:** Epoetin alfa Global study – 18 countries	Haemoglobin response	• FPD: Q4 13 • Est. completion: 2017 Sponsored by FibroGen

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Tremelimumab (CTLA-4 mAb)

Mesothelioma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **DETERMINE** **NCT01843374**	Patients with unresectable pleural or peritoneal malignant mesothelioma 2L or 3L treatment	N = 564	• **Arm 1:** Tremelimumab IV • **Arm 2:** Placebo • US, EU, and Asia • 19 Countries	• Primary: Overall survival (OS) Secondary: • Durable disease control rate by treatment arm • Length of progression-free survival by treatment arm • Overall response rate by treatment arm	• FPD: Q2 13 • LPD: Q4 14 • Topline results: H1 16 • Est. completion date: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Durvalumab (MEDI4736; PD-L1 mAb)

Non-small cell lung cancer (NSCLC)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III ADJUVANT **NCT02273375** **Partnered with NCIC CTG**	Adjuvant NSCLC patients IB (≥4cm) – IIIA resected NSCLC (incl. EGFR/ALK pos)	N = 1,100	• Arm 1: MEDI4736 mg/kg IV Q4W x 12 mos • Arm 2: Placebo Global Study	• DFS • OS	• FPD: Q1 15 • Est. completion: 2020
Phase III PACIFIC **NCT02125461**	Unresectable Stage III NSCLC patients following platinum-based concurrent chemo-radiation therapy	N = 702	• Arm 1: MEDI4736 IV Q2W • Arm 2: placebo Global study	• Progression Free Survival (PFS) • Overall Survival (OS)	• FPD: Q2 14 • LPD: H1 16 • Est. completion: 2017
Phase II/III Lung Master Protocol **NCT02154490** **Partnered with NCI, FNIH, and SWOG**	Stage IV squamous NSCLC patients Biomarker-targeted 2L therapy	N = 140 ; 100 Durvalumab treated (4736 substudy only);	Umbrella study with 5 arms based on biomarker expression • Substudy A: MEDI4736 (non-match for other biomarker driven substudies) IVQ2W single arm MEDI4736 PhII only • Substudy B: PI3K Inhibitor vs. docetaxel • Substudy C: CDK4/6 inhibitor vs. docetaxel • Substudy D: AZD4547 (FGFR inhibitor) vs. docetaxel • Substudy E: C-MET/HGFR Inhibitor + erlotinib vs. Erlotinib (Substudy is closed)	Arm 1 • ORR, PDL1 +	• FPD: Q2 14 • Est. completion: 2022
Phase II ATLANTIC **NCT02087423**	Stage IIIB-IV NSCLC patients PD-L1+ve patients 3L	N = 293	• Arm 1: MEDI4736 IV Q2W (EFGR/ALK WT) • Arm 2: MEDI4736 IV Q2W (EFGR/ALK M+) • Arm 3: MEDI4736 IV Q2W (EFGR/ALK WT) (90% PD-L1 - expression) Global study – 18 countries	• Objective Response Rate • Secondary endpoints include duration of response, progression free survival and overall survival	• FPD: Q1 14 • LPD: Q2 15 • First data: Q4 15 • Est. completion: H2 16 • Filing not expected

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Durvalumab (MEDI4736; PD-L1 mAb)

SCCHN and other solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **HAWK** **NCT02207530**	SCCHN 2L PD-L1 positive	N = 112	• Single-arm: MEDI4736 IVQ2W	• ORR	• FPD: Q1 15 • LPD: H1 16 • Est. completion: H2 16
Phase I **NCT02301130** **Partnered with KHK**	Solid tumours	N = 108	• Dose Escalation: N=36, 3 cohorts receiving Treatment A (mogamulizumab+MEDI4736) and 3 cohorts receiving Treatment B (mogamulizumab+treme), in parallel • Dose Expansion: N=72, Multiple solid tumour types (NSCLC, Head and Neck, Pancreatic), Treatment A or B (12 subjects per treatment per disease type, in parallel)	• Safety and Tolerability • MTD • ORR, DoR, DCR, PFS, OS	• FPD: Q4 14 • LPD: Q4 15 • Est. completion: H2 16
Phase I **NCT01938612**	Solid tumours (all-comers)	N = 118	• Dose Escalation: 3 cohorts at Q2W and 1 cohort at Q3W • Dose Expansion: Multiple solid tumour types Study conducted in Japan	• Safety • Optimal biologic dose	• FPD: Q3 13 • LPD: Q4 14 • Est. completion: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **ARCTIC** **NCT02352948**	Stage IIIB-IV 3L NSCLC patients who have not be tested positive for EGFR/Alk mutation	N = 480	• Arm 1: MEDI4736+tremelimumab (PD-L1 –ve patients) • Arm 2: Standard of Care • Arm 3: tremelimumab (PD-L1 –ve patients) • Arm 4: MEDI4736 (PD-L1 –ve patients)	• Progression Free Survival (PFS) • Overall Survival (OS) • Safety	Combination therapy • FPD: Q2 15 • LPD: H1 16 • Est. completion: 2017 (PFS, OS)
Phase III **MYSTIC** **NCT02453282**	NSCLC 1L	N = 675	• Arm 1: MEDI4736 • Arm 2: MEDI4736 + tremelimumab • Arm 3: Standard of care	• Progression Free Survival • Overall Survival • Safety	• FPD: Q3 15 • LPD: H2 16 • Est. completion: 2017
Phase III **NEPTUNE**	NSCLC 1L	N = 800	• Arm 1: MEDI4736 + tremelimumab • Arm 2: Standard of care	• Overall Survival • Safety	• FPD: Q4 15 • LPD: 2017 • Est. completion: 2018
Phase III **EAGLE**	SCCHN 2L	N = 720	• Arm 1: MEDI4736 + tremelimumab • Arm 2: MEDI4736 • Arm 3: SoC	• Overall Survival • Progression Free Survival • Safety	• FPD: Q4 15 • LPD: 2017 • Est. completion: 2018
Phase III **KESTREL** **NCT02551159**	SCCHN 1L	N = 628	• **Arm 1:** MEDI4736 • **Arm 2:** MEDI4736 + tremelimumab • **Arm 3:** Standard of care	• Progression Free Survival (PFS) • Overall Survival (OS) • Safety	• FPD: Q4 15 • LPD: 2017 • Est. completion: 2018
Phase III **DANUBE** **NCT02516241**	Bladder 1L cis eligible and ineligible	N = 525	• **Arm 1:** MEDI4736 + tremelimumab • **Arm 2:** MEDI4736 • **Arm 3:** SoC	• Progression free Survival • Overall Survival • Safety	• FPD: Q4 15 • LPD: 2017 • Est. completion: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II CONDOR **NCT02319044**	SCCHN 2L PD-L1 negative	N = 240	• Arm 1: MEDI4736 • Arm 2: Tremelimumab • Arm 3: Tremelimumab + MEDI4736	• ORR • Safety	• FPD: Q2 15 • LPD: H1 16 • Est. completion: 2017
Phase II ALPS **NCT02558894**	Metastatic Pancreatic Ductal Carcinoma 2L	N = 130	• Arm 1: MEDI4736 + tremelimumab • Arm 2: MEDI4736	• Safety • Objective Response rate • Pharmacokinetics	• FPD: Q4 15 • LPD: 2017 • Est. completion: 2017
Phase I combination in advanced solid tumours in Japanese patients **NCT02141347**	Solid tumors (treme Phase I)	N = 22	• Tremelimumab + MEDI4736 • Dose Escalation study • Tremelimumab Q4W/Q12W 3-10mg/kg • Tremelimumab Q4W/Q12W X mg/kg + MEDI4736 Q4W X mg/kg	• Safety • Optimal biologic dose	• FPD: Q2 14 • LPD: Q2 15 • Est. completion: Q3 15

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Cediranib (VEGF inhibitor)

Ovarian cancer

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **ICON 6** **NCT00532194**	Patients with platinum-sensitive relapsed ovarian cancer	N = 486	• **Arm 1:** Placebo • **Arm 2:** concurrent cediranib • **Arm 3:** concurrent and maintenance cediranib	• Progression Free Survival	• FPD: Q2 07 • Completed

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Moxetumomab pasudotox (CD22 mAb)

Haematological malignancies

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **PLAIT** **NCT01829711**	Adults with relapsed or refractory hairy cell leukemia	N = 77	• Multicentre, single-arm, open-label study3	• Primary: Rate of durable CR: CR maintained for > 180 days • Efficacy: CR rate, ORR, Duration of CR and ORR, time to response (TTR), PFS • Safety and tolerability • PK and immunogenicity	• FPD: Q2 13 • LPD: H2 16 • Est. topline results: 2017
Phase I **NCT00586924**	Adults with relapsed refractory HCL	N = 49	• Open Label dose escalation study	• MTD and efficacy	• FPD: Q2 07 • LPD: Q1 14 • Topline results : Q2 15 (completed)

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Selumetinib (AZD6244) (MEK-inhibitor)

Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III **SELECT-1** **NCT01933932**	2L KRASm positive NSCLC	N = 500	• **Arm 1:** Selumetinib 75mg BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle • **Arm 2:** Placebo BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle Global study – 26 countries	• Progression Free Survival • Overall Survival is a secondary endpoint	• FPD: Q4 13 • LPD: H1 16 • Est. topline results: H2 16
Phase III **ASTRA** **NCT01843062**	Differentiated thyroid cancer	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)	• FPD: Q3 13 • LPD: H1 16 • Est. topline results: 2017
Phase II **SELECT-2** **NCT01750281**	2L KRASm negative NSCLC	N = 225	• **Arm 1:** Selumetinib 75mg BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle • **Arm 2:** Selumetinib 75mg BiD + docetaxel 60 mg/m2 IV on day 1 of each 21 day cycle • **Arm 3**: Placebo BiD + docetaxel 75 mg/m2 IV on day 1 of each 21 day cycle Global study – 7 countries	• Progression Free Survival • Overall Survival is a secondary endpoint	• FPD: Q1 13 • LPD: Q4 15 • Est. topline results: H1 16

Phase II
 	
NCT01362803 (current Ph I) – partnered (NCI)
	Pediatric NF1[1]	N = minimum of 50 symptomatic pts	• **Single Arm:** Selumetinib 25mg/m^2 BID with 2 strata:
			  • Stratum 1: PN related morbidity present at enrolment
			  • Stratum 2: No PN related morbidity present at enrolment
				• Complete partial and complete response rate measured by volumetric MRI;
				• Duration of response and functional outcomes/QoL
					• FPD: Q3 15
					• LPD: H2 16
					• Est. topline results: 2017

Phase I **NCT02586987**	Advanced solid tumours	N = 40	• **Dose escalation study:** Starting dose Selumetinib 50mg bd 1 week on/1 week off - MEDI4736 20mg/kg Q4 – after 7 days of selumetinib dosing. • Note: No escalation in MEDI4736 dose; Selumetinib escalation with 25 mg bd increment / dose cohort	• Safety and tolerability • PK of Selumetinib and MEDI4736 and preliminary anti-tumour activity	• FPD: Q4 15 • LPD: H2 16 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Acalabrutinib (ACP-196)

Haematological malignancies

Study phase	Patient population	Number of patients	Design	Endpoint(s)	Status
Phase III	Previously treated patients with high risk CLL	N = 500	• **Arm A:** acalabrutinib • **Arm B:** ibrutinib	PFS Secondary endpoints include comparison of incidence of infections, RTs and atrial fibrilation	FPD: Q4 15
Phase III	Patients with previously untreated CLL	N = 510	• **Arm A:** obinutuzumab + Chlorambucil • **Arm B:** acalabrutinib +obinutuzumab • **Arm C:** acalabrutinib	PFS Secondary endpoints include IRC assessed ORR, TTNT, and OS	FPD: Q3 15
Phase II	Previously treated patients with MCL	N = 117	• Acalabrutinib monotherapy	ORR Secondary endpoints include safety, DOR, PFS, and OS	FPD: Q1 15
Phase II	Patients with WM	N = 88	• Acalabrutinib monotherapy	ORR Secondary endpoints include IRC assessed ORR, DOR, and PFS	FPD: Q3 14
Phase II	Patients with advanced or metastatic pancreatic cancer	N = 76	• **Arm A:** acalabrutinib • **Arm B:** acalabrutinib+ pembrolizumab	Safety (TEAEs, SAEs, DLTs, AEs of clinical interest, or AEs leading to discontinuation) Secondary endpoints include disease control rate (DCR), ORR, DOR, PFS, and OS	FPD: Q2 15
Phase II	Patients with platinum-refractory metastatic bladder cancer	N = 74	• **Arm A:** pembrolizumab • **Arm B:** acalabrutinib+ pembrolizumab	Safety (TEAEs, SAEs, DLTs, AEs of clinical interest, or AEs leading to discontinuation) Secondary endpoints include BOR and ORR, DOR, PFS, and OS	FPD: Q2 15

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Acalabrutinib (ACP-196)

Haematological malignancies

Study phase	Patient population	Number of patients	Design	Endpoint(s)	Status
Phase II	Patients with advanced head and neck squamous cell carcinoma	N = 74	• **Arm A:** pembrolizumab • **Arm B:** acalabrutinib+ pembrolizumab	Safety (TEAEs, SAEs, DLTs, AEs of clinical interest, or AEs leading to discontinuation) Secondary endpoints include ORR, DCR, DOR, PFS, and OS	FPD: Q2 15
Phase II	Patients with advanced NSCLC	N = 74	• **Arm A:** pembrolizumab • **Arm B:** acalabrutinib+ pembrolizumab	Safety (TEAEs, SAEs, DLTs, AEs of clinical interest, or AEs leading to discontinuation) Secondary endpoints include disease control rate (DCR), ORR, DOR, PFS, and OS	FPD: Q2 15
Phase II	Patients with recurrent ovarian cancer	N = 76	• **Arm A:** acalabrutinib • **Arm B:** acalabrutinib+ pembrolizumab	Safety (TEAEs, SAEs, DLTs, AEs of clinical interest, or AEs leading to discontinuation) Secondary endpoints include BOR and ORR, DOR, PFS, and OS	FPD: Q4 15
Phase II	Patients with previously untreated metastatic pancreatic cancer	N = 120	• **Arm A:** acalabrutinib+ Nab-Paclitaxel+ Gemcitabine • **Arm B:** Nab-Paclitaxel+ Gemcitabine	ORR, DOR, PFS, OS, change in CA 19-9 antigen Secondary endpoints include safety (TEAEs, SAEs, DLTs, AEs of clinical interest, or AEs leading to discontinuation)	FPD: Q4 15
Phase I/II	Patients with CLL, SLL, PLL	N = 286	• Dose escalation study of in multiple disease settings including TN, RR, and RT	Safety, PK, PD Secondary endpoints include ORR, DOR, and PFS	FPD: Q1 14

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

CAZ AVI (BLI/cephalosporin SBI)

Serious infections

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase III RECAPTURE-1 **NCT01595438**	Hospitalised adults with complicated urinary tract Infections	N = 563	• **Arm 1:** CAZ-AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • **Arm 2:** Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim Global study – 26 countries	• Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT)	• FPD: Q4 12 • LPD: Q3 14 • Topline results: Q3 15
Phase III RECAPTURE-2 **NCT01599806**	Hospitalised patients with complicated urinary tract infections	N = 583	• **Arm 1:** CAZ-AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • **Arm 2:** Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim Global study – 25 countries	• Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT)	• FPD: Q4 12 • LPD: Q3 14 • Topline results: Q3 15
Phase III REPRISE **NCT01644643**	Patients with complicated urinary tract infections and complicated intra-abdominal infections	N = 345	• **Arm 1:** CAZ-AVI 2000/500mg plus Metronidazole IV • **Arm 2:** Best available therapy Global study – 30 countries	• Patients with clinical cure at the Test of Cure visit in the microbiological intent to treat analysis set	• FPD: Q1 13 • LPD: Q3 14 • Topline results: Q2 15
Phase III RECLAIM-3 **NCT01726023**	Hospitalised patients with complicated intra-abdominal infections	N = 486	• **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	• FPD: Q1 13 • LPD: Q1 15 • Topline results: Q3 15
Phase III REPROVE **NCT01808092**	Hospitalised patients with nosocomial pneumonia infections, including hospital acquired pneumonia (HAP) and ventilator associated pneumonia (VAP)	N = 1,000	• **Arm 1:** 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)	• FPD: Q2 13 • LPD: Q4 15 • Est. topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD3293 (BACE inhibitor)

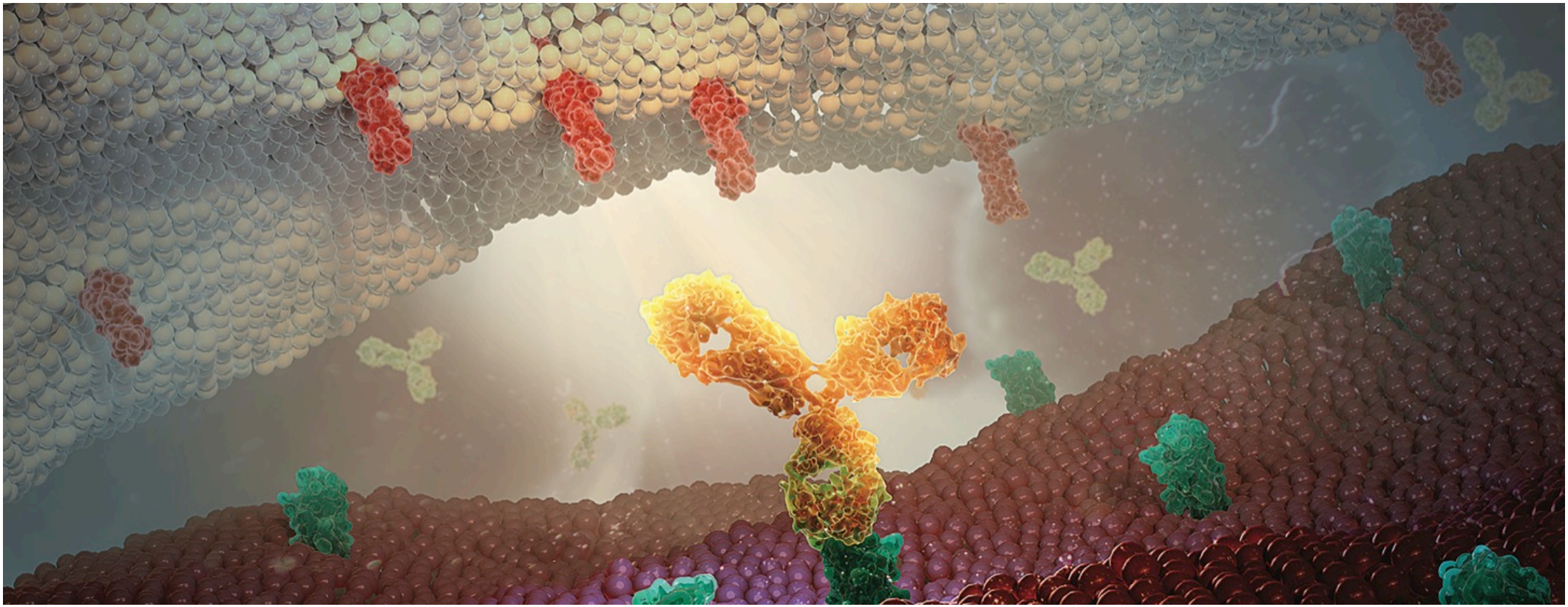
Alzheimer's disease

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II/III **AMARANTH** **NCT02245737**	Alzheimer's disease patients	N = 2,202	• **Arm 1:** AZD3293 20 mg once daily • **Arm 2:** AZD3293 50 mg once daily • **Arm 3:** placebo once daily 24-month treatment duration Global study – approx. 15 countries	• Change in Clinical Dementia Rating Sum of Boxes (CDR-SB) • Changes in Cognitive (ADAS-Cog 13) and functional (ADCS-ADL) scales • Changes in biomarkers and imaging assays • Safety and tolerability	• FPD: Q4 14 • LPD: 2017 • Est. topline results: 2019

AstraZeneca

AstraZeneca
IMED Biotech Unit

Early development - IMED



Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD7594 (inhaled SGRM)

Asthma/COPD

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02479412**	Patients with mild to moderate asthma	N = 48	**Sequence 1** Placebo once daily for 14 days, 58 µg AZD7594 once daily for 14 days and 250 µg AZD7594 once daily for 14 days **Sequence 2** Placebo once daily for 14 days, 250 µg AZD7594 once daily for 14 days and 800 µg AZD7594 once daily for 14 days **Sequence 3** Placebo once daily for 14 days, 800 µg AZD7594 once daily for 14 days and 58 µg AZD7594 once daily for 14 days **Sequence 4** 58 µg AZD7594 once daily for 14 days, Placebo once daily for 14 days and 800 µg AZD7594 once daily for 14 days **Sequence 5** 58 µg AZD7594 once daily for 14 days, 800 µg AZD7594 once daily for 14 days and Placebo once daily for 14 days **Sequence 6** 250 µg AZD7594 once daily for 14 days, Placebo once daily for 14 days and 58 µg AZD7594 once daily for 14 days **Sequence 7** 250 µg AZD7594 once daily for 14 days, 58 µg AZD7594 once daily for 14 days and Placebo once daily for 14 days **Sequence 8** 800 µg AZD7594 once daily for 14 days, Placebo once daily for 14 days and 250 µg AZD7594 once daily for 14 days **Sequence 9** 800 µg AZD7594 once daily for 14 days, 250 µg AZD7594 once daily for 14 days and Placebo once daily for 14 days	• Forced expiratory volume in one second (FEV1)	• FPD: Q3 15 • Ongoing
Phase I **NCT01636024**	Healthy subjects	N = 73	**SAD/MAD** A Phase I, Single Centre, Double-blind, Randomised, Placebo controlled, Parallel-group Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics After Single and Multiple Ascending Inhaled Doses of AZD7594 in Healthy Male Volunteers - Suspension inhaled via Spira nebuliser Study conducted in the UK	• Safety and tolerability	• FPD: Q4 12 • Completed

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD7624 (p38 inhibitor)

COPD

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **NCT02238483**	COPD	N = 212	• **Arm 1**: AZD7624, 1.0mg • **Arm 2**: placebo • Inhaled (nebulised) administration Study conducted in US, EU, South Africa & South America	• Effect on rate of exacerbations and lung function compared to placebo	• FPD: Q4 14 • LPD: H1 16 • Est. topline results: H1 16
Phase Ib **LPS** **NCT01937338**	Healthy subjects	N = 30	• 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	• FSD: Q4 13 • Completed
Phase I **NCT01754844**	Healthy subjects	N = 48	**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	• FSD: Q1 13 • Completed
Phase I **NCT01817855**	Healthy subjects and COPD	N = 47	**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	• FSD: Q3 13 • Completed

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD7986 (DPP1 inhibitor)

COPD

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02303574**	Healthy subjects	N = 152	**Part 1 (SAD)** • Five different dose levels investigated vs placebo • oral administration	• Safety and tolerability and PK following oral administration with single ascending dose • Preliminary assessment of the effect of food on the single dose PK parameters of AZD7986	• FPD: Q4 14 • Completed
			Part 2 (MAD) • Three different dose levels investigated vs placebo in healthy volunteers • oral administration Study conducted in the UK	• Safety and tolerability & PK in healthy subjects following administration of multiple ascending oral doses • NE activity	• FPD: Q1 15 • LPD: H1 16 • Est. completion: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD8999 (MABA1)

Asthma/COPD

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02059434**	Part 1: Mild Asthmatic Part 2: Moderate to severe COPD	N (Part 1) = 17 N (Part 2) = 38	**Part 1** SAD study with 6 dose levels - 5 µg, 20 µg, 50 µg, 100 µg, 200 µg, and up to 400 µg **Part 2** Comprises 5 treatment periods of 36 hours each separated by a washout period of at least 7 to 14 days (one exception per patient of up to 28 days would be acceptable). • AZD8999 100 µg once daily (double-blind) • AZD8999 400 µg once daily (double-blind) • Indacaterol 150 µg once daily (open-label) • Tiotropium 18 µg once daily (open-label) • Placebo (double-blind) Global Study – 1 country	**Part 1 Endpoints:** • To assess the safety and tolerability of single doses of AZD8999 administered by inhalation to mild persistent asthmatic male subjects • To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8999 in mild persistent asthmatic male subjects **Part 2 Endpoints:** • To assess the safety and tolerability of single doses of AZD8999 administered by inhalation to moderate to severe COPD subjects • To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8999 in moderate to severe COPD subjects	Part 1 • FPD: Q4 13 • LPD: Q1 14 Part 2 • FPD: Q2 14 • LPD: Q3 14 Study completed

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD8871 (MABA2)

Asthma/COPD

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **CTs.gov Identifier:** **In progress**	Part 1: Mild Asthmatic Part 2: Moderate to severe COPD	N (Part 1) = 16 N (Part 2) = 40	**Part 1** SAD study with 6 planned dose levels - 50 µg, 100 µg, 300 µg, 600 µg, 1200 µg, and up to 1800 µg **Part 2** Comprises 5 treatment periods of 36 hours each separated by a washout period of at least 7 to 14 days (one exception per patient of up to 28 days would be acceptable). • AZD8871 dose A once daily (double-blind) • AZD8871 dose B once daily (double-blind) • Indacaterol 150 µg once daily (open-label) • Tiotropium 18 µg once daily (open-label) • Placebo (double-blind) Global Study – 1 country	**Part 1 Endpoints:** • To assess the safety and tolerability of single doses of AZD8871 administered by inhalation to mild persistent asthmatic male subjects • To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8871 in mild persistent asthmatic male subjects **Part 2 Endpoints:** • To assess the safety and tolerability of single doses of AZD8871 administered by inhalation to moderate to severe COPD subjects • To evaluate the pharmacodynamics (PD) (bronchodilation) of single doses of AZD8871 in moderate to severe COPD subjects	Part 1 • FPD: Q4 15 • LPD: H1 16 Part 2 • FPD: H1 16 • LPD: H2 16 Est. completion date: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD9412 (Inhaled IFN-beta)

Asthma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **INEXAS** **NCT02491684**	Asthma	N = 220	• **Arm 1:** 24 µg (metered dose) AZD9412 once daily for 14 days • **Arm 2:** Placebo once daily for 14 days • Inhaled nebulised administration Conducted in Argentina, Australia, Colombia, France, Spain, South Korea and UK.	• Proportion of patients with a severe asthma exacerbation during 14 days of treatment	• FPD: Q3 15 • LPD: H2 16 • Est. topline results: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

RDEA3170 (SURI, URAT1 inhibitor)

Gout and hyperuricemia development programme

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01927198**	Monotherapy study in subjects with gout	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	• FPD: Q3 13 • LPD: Q4 13 • Study complete
Phase II **NCT02078219**	Monotherapy study in Japanese patients with gout or asymptomatic hyperuricemia	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 Allopurinol 100mg BID	• To compare the efficacy of RDEA3170 monotherapy at Week 16 with placebo and allopurinol	• FPD: Q1 14 • LPD: Q3 14 • Study complete
Phase II **NCT02246673**	Combination therapy study with febuxostat in subjects with gout	N = 60	• **Arm A**: RDEA3170 2.5 mg QD • **Arm B**: RDEA3170 5.0 mg QD • **Arm C**: RDEA3170 10 mg QD • **Arm D**: RDEA3170 15 mg QD • **Arm E**: Sequential doses of RDEA3170 10, 15 and 20 mg QD in combination with 40 mg QD febuxostat *Arms A-D include combination with 40 mg QD febuxostat for 7 days followed by combination with 80 mg QD febuxostat for 7 days	• To assess the PK and PD profiles of RDEA3170 administered with febuxostat	• FPD: Q4 14 • LPD: Q2 15 • Est. completion: H1 16
Phase II **NCT02317861**	Combination study with febuxostat for treating gout or asymptomatic hyperuricemia in Japanese patients	N = 92	• **Arm A**: RDEA3170 2.5 mg QD + 10mg or 20mg QD febuxostat • **Arm B**: RDEA3170 5.0 mg QD + 10mg or 20mg QD febuxostat • **Arm C**: RDEA3170 5.0 mg QD + 20mg or 40mg QD febuxostat • **Arm D**: RDEA3170 10 mg QD + 20mg or 40mg QD febuxostat • **Arm E**: Benzbromarone 50 mg QD	• To assess the PD, PK and safety profiles of RDEA3170 administered with febuxostat	• FPD: Q4 14 • LPD: Q2 15 • Est. completion: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

RDEA3170 (SURI, URAT1 inhibitor)

Gout and hyperuricemia

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02498652**	Combination therapy study with allopurinol in subjects with gout	N = 40	• **Arm A**: Placebo • **Arm B:** RDEA3170 2.5 mg QD • **Arm C**: RDEA3170 5.0 mg QD • **Arm D**: RDEA3170 7.5 mg QD • **Arm E**: RDEA3170 10 mg QD • **Arm F**: RDEA3170 15 mg QD • **Arm G**: RDEA3170 20 mg QD *All arms include combination with 300 mg QD allopurinol. Placebo group also includes combination with 300 mg BID allopurinol or 600 mg QD allopurinol	• To assess the PK and PD profiles of RDEA3170 administered with allopurinol	• FPD: Q3 15 • LPD: Q4 15 • Est. completion: H1 16
Phase I **NCT02608710**	Pharmacokinetic and Pharmacodynamic study in healthy adult male subjects	N = 40	**Part 1:** Single doses of RDEA3170 at 4.5 mg, 6.0 mg, or 12 mg **Part 2:** Multiple doses of RDEA3170 at 12 mg QD for 7 days **Part 3:** Food effect study with single doses of RDEA3170 at 6.0 mg	• To assess the PK, PD and food effect profiles of RDEA3170	• FPD: Q4 15 • LPD: Q4 15 • Est. completion: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD9567 (oSGRM)

Rheumatoid Arthritis

Study phase	Patient population	Number of subjects	Design	Endpoints	Status
Phase I **NCT02512575**	Healthy Volunteers	N = 72	SAD study with 6 dose levels - 2 µg, 10 µg, 40 µg, 100 µg, 200 µg, and up to 400 µg Global Study – 1 country	• A Phase I, Randomized, Single-Blind, Placebo-Controlled Study To Assess The Safety, Tolerability, Pharmacokinetics And Pharmacodynamics Of Single Ascending Oral Doses Of AZD9567 In Healthy subjects	Part • FPD: Q4 15 • LPD: H1 16 • Est. top-line results: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD9977 (mineralocorticoid receptor modulator)

Diabetic kidney disease

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02484729**	Healthy subjects	N = up to 88	**Part A: Single Ascending Dose (SAD) study** • Up to 8 different dose levels investigated vs placebo • Oral administration	• Safety and tolerability • PK parameters	• FPD: Q3 15 • LPD: Q4 15 • Terminated
			Part B: Cross-over study to assess regional absorption • Oral administration using IntelliCap® and an oral solution Study conducted in the UK	• PK parameters • Safety and tolerability	• FPD: Q3 15 • LPD: Q4 15 • Terminated
Phase I **NCT02532998**	Healthy subjects	N = up to 24	**Adaptive cross-over study with 4-6 treatment periods** • Comparators include eplerenone and placebo • Fludrocortisone used as challenge agent • Oral administration Study conducted in the UK	• Effects on urinary electrolyte excretion • Safety and tolerability	• FPD: Q3 15 • LPD: Q4 15 • Terminated
Phase I **NCT02560363**	Healthy subjects	N = up to 12	**Part A: Adaptive cross over study with 3 or 4 treatment periods** • Assessment of 3 or 4 formulations • Oral administration Study conducted in the UK	• PK parameters • Safety and tolerability	• FPD: Q4 15 • LPD: H1 16 • Terminated
			Part B: Cross over study with 2 treatment periods • Oral administration Study conducted in the UK	• PK parameters • Safety and tolerability	• FPD: Q4 15 • LPD: H1 16 • Terminated

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD4901 (NK3 Receptor Antagonist)

Phase II clinical development programme

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **NCT01872078**	Polycystic ovary syndrome patients with amenorrhea or oligomenorrhea	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	• Completed: Q4 14 • Divested to Millendo Therapeutics, Inc. Agreement announced January 2016.

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD4076 (anti-miR 103/107)

Non-alcoholic Steatohepatitis (NASH)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02612662**	Healthy subjects	N = up to 48	**Single Ascending Dose (SAD) study** • Up to 6 different dose levels investigated vs placebo • Sc injection	• Safety and tolerability • PK parameters	• FPD: Q4 15 • LPD: H2 16 • Est. completion: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD1775 (WEE-1)

Solid tumours, ovarian cancer and non-small cell lung cancer

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01357161** Partnered	p53 mutant PSR ovarian cancer	N = 120	• **Arm 1:** carbo/paclitaxel + AZD1775 225mg • **Arm 2:** carbo/paclitaxel + placebo Global study 10 countries	• Progression Free Survival • Secondary endpoint: Overall Survival	• FPD: Q4 12 • LPD: H2 16 • Est. completion: H2 16 • Note: Data collection for primary outcome measure completed Q4 2014
Phase II **NCT02272790**	p53 mutant PR ovarian cancer	N = 173	• **Arm 1:** chemotherapy + AZD1775 225mg • **Arm 2:** chemotherapy Global study	• Progression Free Survival • Secondary endpoint: Overall Survival	• FPD: Q1 15 • LPD: H2 16 • Est. completion: 2017
Phase I/II **NCT02482311**	p53 mutant advanced solid tumours	N = 132	• **Monotherapy** Safety Run-in (part A, N=12); solid tumours Expansions into specific tumour types, inc ovarian cancer (failed PARP-inhibitor) , triple negative breast cancer (TNBC) and squamous non-small cell lung cancer (SqNSCLC) Conducted in US, Canada	• Safety and tolerability • Secondary endpoints: Progression Free Survival and Overall Survival	• FPD: Q3 15 • LPD: H2 16 • Est. completion: 2017
Phase I **NCT02610075**	p53 mutant advanced solid tumours	N = 18	• **Monotherapy** Dose escalation study to determine MTD Conducted in US	• Safety and tolerability	• FPD: Q4 15 • LPD: H2 16 • Est. completion: 2017
Phase I **NCT02511795**	p53 mutant advanced solid tumours	N = 36	• **Dose escalation study (AZD1775 + olaparib)** Conducted in US	• Safety and tolerability	• FPD: Q3 15 • LPD: H1 16 • Est. completion: H1 16
Phase I **NCT02617277**	p53 mutant advanced solid tumours	N = 18	• **Dose escalation study (AZD1775 + MEDI4736)** Conducted in US	• Safety and tolerability	• FPD: Q4 15 • LPD: H2 16 • Est. completion: 2017
Phase I **NCT02341456**	p53 mutant advanced solid tumours	N = 18	• **Dose escalation study (AZD1775 + carboplatin + paclitaxel)** Conducted in Australia, Japan and Republic of Korea	• Safety and tolerability	• FPD: Q1 15 • LPD: H2 16 • Est. completion: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Savolitinib (AZD6094) (MET)

Papillary renal cell and other cancers

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT02127710**	Papillary renal cell cancer	N = 90	• Single arm study: AZD6094 600mg QD Conducted in UK, Spain, US, Canada	• Overall Response Rate	• FPD: Q2 14 • LPD: Q4 15 • Est. completion: H1 16
Phase I **NCT01773018** Partnered	Advanced cancer (all-comers)	N = 50	• Dose escalation study Conducted in Australia	• Safety and tolerability	• FPD: Q1 12 • LPD: Q3 15 • Est. completion: H1 16
Phase I **NCT01985555** Partnered	Advanced cancer (all comers)	N = 70	• Dose escalation study Conducted in China	• Safety and tolerability	• FPD: Q2 13 • LPD: H2 16 • Est. completion: 2017
Phase I **NCT02252913** Partnered	Advanced gastric cancer (all-comers)	N = 50	• Dose escalation study Conducted in China	• Safety and tolerability	• FPD: Q4 14 • LPD: H1 16 • Est. completion: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD2014 (TORC 1/2)
Breast and squamous NSCLC cancer

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **STORK** **NCT02403895**	Relapsed or refractory squamous non-small cell lung cancer (at least one prior therapy)	N = 40	Open label Single arm – patient are divided in two groups Group A - intensive PK Group B – sparse PK Dose: intermittent AZD2014 50mg BID (3 days on +4 days off) + weekly paclitaxel 80 mg/m^2 Multicentre: EU and US study sites	• Primary: ORR according to RECIST 1.1 by Investigator assessment • Secondary: Number of patients experiencing adverse events (AE) and Serious Adverse Events (SAEs) including chemistry, haematology, vital signs and ECG variables	• FPD: Q2 15 • LPD: H2 16 • Est. completion: 2017
Phase II **MANTA** **NCT02216786** Partnered	2nd line ER+ metastatic breast cancer	N = 316	• **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 • Secondary endpoint: Overall Survival	• FPD: Q2 14 • LPD: H1 16 • Est. completion: 2017
Phase I **NCT02398747**	Japanese Patients with Advanced Solid Malignancies	N = 18	Open label Monotherapy and combination with paclitaxel cohorts	• Safety and tolerability of AZD2014 monotherapy and in combination with paclitaxel • PK	• FPD: Q2 15 • LPD: H1 16 • Est. completion: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD3759 (EGFRm BBB)

Lung cancer with lung and/or brain metastases

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **BLOOM** **NCT02228369**	EGFRm+ NSCLC	N = 47	• MAD • Expansion in LM patients at RP2D with AZD3759 • Expansion in 12 LM patients at 160mg with AZD9291 Study conducted 4 countries	• Safety and tolerability • Preliminary anti-tumour activity	• FPD: Q4 14 • Est. completion: LM expansion at RP2D H2 16 • AZD9291 LM expansion • Est. topline results: Q4 15

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD4547 (FGFR)
Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II/III Lung Master Protocol **NCT02154490** Partnered with NCI and SWOG	Stage IIIB-IV NSCLC patients Biomarker-targeted 2L therapy	N = 318 (AZD4547 arm only)	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)	• FPD: Q4 14 • Est. completion: 2022 (final data collection for primary outcome measure Ph III)

Phase II
GLOW
 	
NCT01202591
	Female ER+ breast cancer patients whose disease has progressed following treatment with one prior endocrine therapy	N = 40	• **Part A:** AZD4547 in ascending multiple doses in combination with 25mg exemestane
			• **Part B:**
			  • **Arm 1:** AZD4547 (dose from part A) + 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
					• LPD: Q2 14
					• Completed: Q1 15

Phase II **SHINE** **NCT01457846**	Advanced gastro-oesophageal cancer	N = 71	• **Arm 1** (FGFR2 polysomy): AZD4547 vs paclitaxel randomized 1:1 (30 to 80 patients) • **Arm 2** (FGFR 2 low gene amplification: AZD4547 vs paclitaxel randomized 3:2 (25 to 80 patients) • **Arm 3** (FGFR2 high gene amplification: AZD4547 vs paclitaxel randomized 3:2 (25 to 80 patients)	• Progression Free Survival • Key Secondary: Overall survival/Tumour size	• Recruitment closed after interim analysis: Q2 13 • Completed: Q1 15
Phase I **NCT01213160**	Advanced cancer who have failed standard therapy or for whom no standard therapy exists	N = 33	• **Part A:** AZD4547 in ascending multiple doses given bd and od (c. 30 patients) • **Part B:** AZD4547 in patients whose tumours have FGFR amplification (c. 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	• Completed: Q2 13

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD4547 (FGFR)
Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT00979134**	Advanced cancer who have failed standard therapy or for whom no standard therapy exists	N = 94	• **Part A:** Ascending oral doses of AZD4547 to define maximum tolerated dose (MTD) and /or continuous, tolerable recommended dose (RD) • **Part B:** Dose expansion phase at RD defined in Part A • **Part C:** Expansion phase in patiens with FGFR1 and FGFR2 amplified tumours at the RD defined from Part A	• **Part A:** MTD and Recommended dose for Parts B and C • **Part B and C:** Safety and tolerability, PK and preliminary anti-tumour activity	• Completed: Q1 14
Phase I **NCT02546661**	2nd+ line Muscle Invasive Metastatic Bladder Cancer in patients who have failed prior therapy	N = 40	• BISCAY - A multi-drug biomarker-directed study of monotherapy AZD4547 and combination therapy AZD4547 + Durvalumab	• Safety and tolerability of the combination • PK and preliminary anti-tumour activity	• FPD Q4 2015 • Est. completion: 2016

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD9496 (SERD)
Breast cancer

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02248090**	ER+ Breast Cancer	N ~150	• This is a Phase I open label multicentre study of AZD9496 administered orally in patients with advanced ER+ HER2 negative breast cancer. The study design allows an escalation of dose with intensive safety monitoring to ensure the safety of patients. The study will determine the maximum tolerated dose. In addition, expansion cohort(s) at potential therapeutic dose(s) in patients with or without ESR1 mutations will be enrolled to further determine the safety, tolerability, pharmacokinetics and biological activity of AZD9496	• Primary Outcome Measures: Safety and tolerability • Secondary Outcome Measures: Single and multiple dose pharmacokinetics of AZD9496 4β-hydroxycholesterol concentration in blood • Anti-tumour activity	• FPD: Q4 14 • Est. completion: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD5312 (ISIS-AR)
Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02144051**	Advanced solid tumours with androgen receptor pathway as a potential factor	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	• FPD: Q2 14 • Est. completion: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD5363 (AKT)
Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIb **NCT01625286**	ER+ breast cancer receiving 1st treatment with paclitaxel in the advanced setting	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	• FPD: Q1 14 • Est. primary completion: 2017 • Est. completion: 2018
Phase I **NCT01226316**	Breast and gynaecological cancers with PIK pathway mutation	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)	• FPD: Q3 13 • Est. primary completion: Q4 15 • Part C Arms 1 & 2 completed • Part D Arms 1, 2 & 3 ongoing
Phase I **NCT01895946**	All-comers solid tumours	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	• Tablet-capsule comparison completed in Q3 14 & formulations declared comparable • Food effect cohort completed in Q2 15

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD6738 (ATR)
Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02264678**	Solid tumours	N = 160	• **Arm 1:** AZD6738 + carboplatin • **Arm 2:** AZD6738 dose escalation AZD6738 + olaparib Study conducted in North America, Europe and South Korea	• Safety and tolerability • Pharmacokinetics and efficacy	• FPD: Q4 14 • Est. completion: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD8186 (PI3Kb/d)
Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT01884285**	Advanced CRPC/SqNSCLC/TNBC and patients with known PTEN-deficient tumours	N = 96	• **Part A:** AZD8186 monotherapy in ascending intermittent doses in 2 schedules • **Part B:** AZD8186 monotherapy at recommended dose and schedule(s) from Part A in PTEN deficient patients with advanced cancer Study conducted in Canada, US & UK	• **Part A:** PK, MTD and Recommended dose and schedule(s) for Part B • **Part B:** Safety and tolerability and preliminary assessment of antitumour activity (POM)	• FPD: Q2 13 • Est. completion: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD8835 (PI3Kα/δ inhibitor)

Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02260661**	Women with estrogen receptor positive HER-2 negative advanced breast cancer with and without PIK3CA mutations	N = 100	• **Part A:** AZD8835 single agent dose escalation • **Part B:** AZD8835 single agent dose expansion • **Part C:** AZD8835 in combination with fulvestrant dose escalation • **Part D:** AZD8835 (at maximum tolerated dose or recommended phase II dose) in combination with fulvestrant dose expansion Study to be conducted in US & UK	• MTD and recommended Phase II dose of oral AZD8835 as a single agent and in combination with fulvestrant. • Safety and tolerability profile of oral AZD8835 as a single agent and in combination with fulvestrant	• FPD: Q4 14 • Est. completion: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD9150 (STAT3)
Solid and Haematological Cancers

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib/II **NCT02499328**	SCCHN	N = 147	**Dose Escalation advanced solid and haematological cancers** • **Arm A1:** AZD9150/MEDI4736 • **Arm A2 :** AZD5069/MEDI4736 **Dose Expansion 2L SCCHN:** • **Arm B1:** AZD9150 • **Arm B2:** AZD5069 • **Arm B3:** AZD9150/MEDI4736 • **Arm B4:** AZD5069/MEDI4736	• Safety/Efficacy Study	• FPD: Q3 15 • LPD: 2017 • Est. completion: 2019

* clinicaltrials.gov being updated

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD0156 (ATM)
Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02588105**	Solid tumours	N = 90	• **Arm 1:** AZD0156 + olaparib • **Arm 2:** AZD0156 + irinotecan Study conducted in North America, Europe and South Korea	• Safety, tolerability, pharmacokinetics and efficacy	• FPD: Q4 15 • Est. completion: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD2811 (AURN)
Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02579226**	Solid tumours	N = 72	• **Arm 1:** AZD2811 dose escalation • **Arm 2:** AZD2811 dose expansion AZD2811 + irinotecan Study conducted in North America	• Safety and tolerability • Pharmacokinetics and efficacy	• FPD: Q4 15 • Est. completion: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

ATM AVI

Infections

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT01689207**	Healthy volunteers		• Randomized, double-blind, 3-part study in healthy young and elderly volunteers given Aztreonam and Avibactam alone and in combination	• Safety/tolerability • Pharmacokinetics (secondary)	• FPD Q4 12 • LPD: Q4 14 • Completion: Q4 15
		N = 12	• **Part A:** single 1 hour IV infusions		
		N = 56	• **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.		
		N = 24	• **Part C**: multiple (every 6 hr) IV infusions Days 1-10 in healthy young and elderly volunteers		
		(Total dosed = 94) *(Total enrolled = 124)*	Single centre in UK		

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD8108 (NMDA)

Phase I clinical development programme

Study phase	Patient population	Number of patients	Design	Endpoints	Status

Phase I
 	
NCT02248818
	Healthy volunteers	N = 40	• Randomized, double-blind, placebo-controlled
			  • Part 1 SAD 3 dosage-level cohorts
			  • Part 2 MAD 2 dosage-level cohorts
			
			US only study, one site
				• Safety and tolerability
				Additional endpoints:
				• Pharmacokinetics
				• Pharmacodynamics
					• FPD: Q4 14
					• LPD: Q3 15
					• Est. topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

AZD3241 (MPO)

Multiple System Atrophy

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01527695**	Parkinson's disease patients	N = 24	• **Arm 1:** AZD3241 600 mg BID for 8 weeks • **Arm 2:** Placeb0 randomisation 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
Phase II **NCT01603069**	Parkinson's disease patients	N = 51	• **Arm 1:** AZD3241 300 mg BID for 12 weeks • **Arm 2:** AZD3241 600 mg BID for 12 weeks • **Arm 3:** Placebo randomisation 1:1:1 across arms 13 sites in US	• AEs, labs, vital signs, ECGs Secondary endpoints: • PD symptoms measured by UPDRS • Plasma MPO activity	• Study completed
Phase II **NCT02388295**	Multiple System Atrophy (MSA)	N = 54	• **Arm 1:** AZD3241 300 mg BID for 12 weeks • **Arm 2:** AZD3241 600 mg BID for 12 weeks • **Arm 3:** Placebo randomisation 1:1:1 across arms 8 sites in US 9 sites in Europe	• Microglia activation represented by [11C]PBR28 binding • AEs, labs, vital signs, ECGs Secondary endpoints: • MSA symptoms measured by UMSARS and MSA QoL • Plasma MPO activity	• FPD: Q2 15 • LPD: H2 16 • Est. topline results: H2 16
Phase I **NCT00729443**	Healthy subjects	N = 46	• **Active ArmS:** SAD • **Comparator Arm:** placebo 1 site in Sweden	• AEs, labs, vital signs, ECGs • PK	• Study completed
Phase I **NCT01457807**	Healthy subjects	N = 18	• **Active ArmS:** MAD • **Comparator Arm:** placebo 1 site in UK	• AEs, labs, vital signs, ECGs • PK	• Study completed
Phase I **NCT00914303**	Healthy subjects	N = 59	• **Active ArmS:** MAD • **Comparator Arm:** placebo 1 site in Sweden	• AEs, labs, vital signs, ECGs • PK	• Study completed

MedImmune

MedImmune
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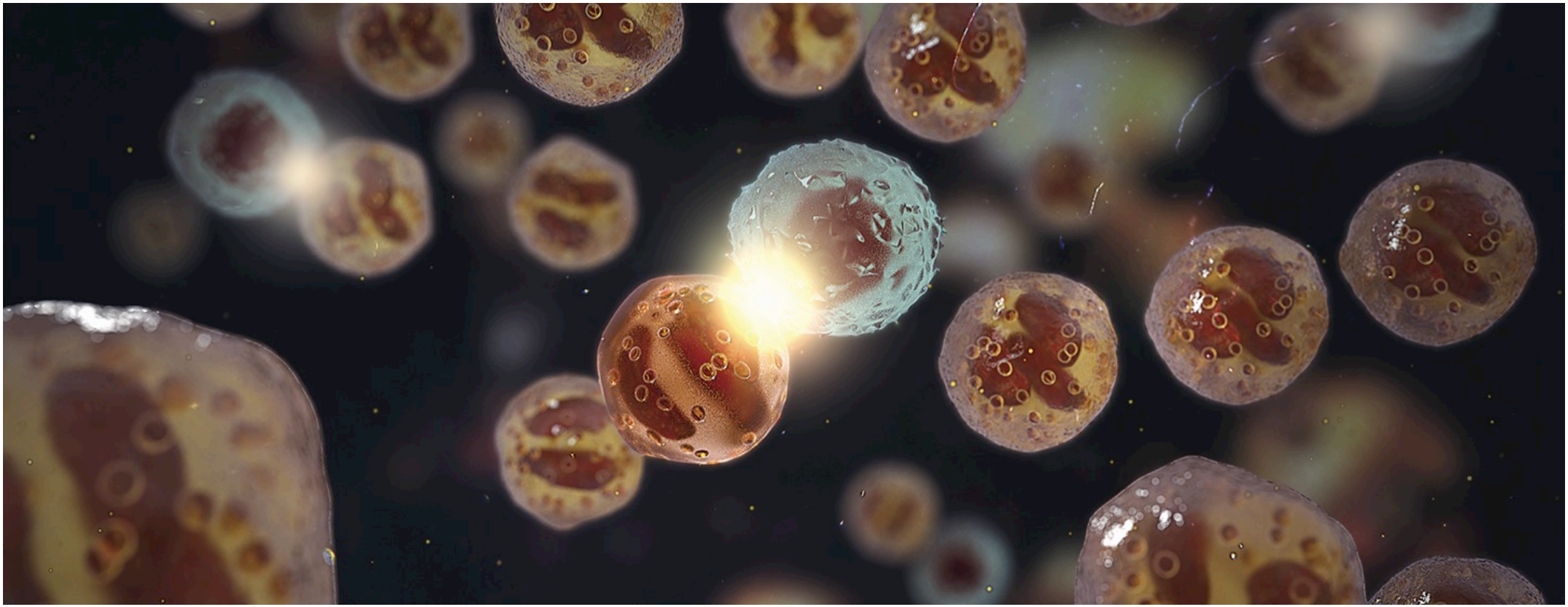
Early development - MedImmune



Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI7836 (IL-13 mAb)

Asthma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02388347**	Healthy volunteers	N = 32	• **Arm 1**: 30 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose • **Arm 2**: 105 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose • **Arm 3**: 300 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose • **Arm 4**: 600 mg MEDI7836 (n = 6) or placebo (n = 2) as a single SC dose	• Safety and tolerability	• FPD: Q1 15 • LPD: Q3 15 • Est. topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI9929 (TSLP mAb)

Asthma

Study phase	Patient population	Design	Endpoints	Status
Phase II **PATHWAY** **NCT02054130** Partnered	Adult subjects with inadequately controlled, severe asthma	• **Arm 1:** Placebo • **Arm 2:** Low dose MEDI9929 70mg SC • **Arm 3:** Medium dose MEDI9929 210mg SC • **Arm 4:** High dose MEDI9929 280mg SC	• Reduction in the annualized asthma exacerbation rate (AER) measured at Week 52	• FPD: Q2 14 • LPD: Q4 15 • Est. topline results: H2 16
Phase II **NCT02525094** Partnered	Adult subjects with moderate-to-severe atopic dermatitis	• **Arm 1:** Placebo • **Arm 2:** Dose of MEDI9929 SC	• 50% reduction from baseline in the Eczema Area and Severity Index measured at Week 12	• FPD: Q2 15 • LPD: H2 16 • Est. topline results: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI5872 (B7RP-1 mAb)

Systemic Lupus Erythematosus (SLE)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase IIa **NCT02334306** Partnered	Primary Sjögren's syndrome	N = 42	• **Arm 1:** MEDI5872 210 mg SC QW for 3 weeks and then Q2W for 9 weeks • **Arm 2:** placebo SC QW for 3 weeks and then Q2W for 9 weeks Global study – 5 countries	• Safety and tolerability • Change in the ESSDAI score from baseline to Day 99	• FPD: Q3 15 • LPD: 2017 • Est. topline results: H1 16
Phase I **NCT01683695** Partnered	SLE and lupus related inflammatory arthritis	N = 40	**Dose escalation study:** • **Arm 1:** MEDI5872 SC • **Arm 2:** placebo SC Global study – 8 countries	• Safety and tolerability • Lupus Arthritis Response Rate	• FPD: Q2 12 • LPD: Q4 15 • Est. topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Mavrilimumab (GMCSF mAb)

Rheumatoid arthritis (RA)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **EARTH Explorer 2** **NCT01715896**	RA patients who have failed 1 or 2 anti-TNF for efficacy, intolerance or safety, OR Inadequate response to DMARDs	N = 138	• **Arm 1:** Mavrilimumab SC • **Arm 2:** golimumab Global study (ex-US) on MTX background; 17 countries	• ACR 20/50/70 at wk 24 • DAS28 remission • Function (HAQ-DI)	• FPD: Q1 13 • LPD: Q3 14 • Topline results: Q4 14
Phase I **NCT02213315**	Healthy Japanese subjects	N = 24	• **Arm 1:** Mavrilimumab medium dose SC • **Arm 2:** Mavrilimumab high dose SC • **Arm 3**: Placebo SC UK Study; Japanese subjects	• Pharmacokinetic profile • Safety and tolerability	• FPD: Q3 14 • LPD: Q3 14 • Topline results: Q4 14

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Other biologics

Inflammation

Compound	Study phase	Patient population	Number of patients	Design	Endpoints	Status
Anti-α4β7 mAb Abrilumab (MEDI7183)	**Phase II** **NCT01694485** Partnered	Moderate to severe ulcerative colitis	N = 359	• **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)	• FPD: Q4 12 • LPD: Q2 15 • Topline results: Q3 15
	Phase II **NCT01696396** Partnered	Moderate to severe Crohn's disease	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)	• FPD: Q4 12 • LPD: Q4 14 • Topline results: Q2 15
	Phase II **NCT01959165** Partnered	Japanese subjects with moderate to severe ulcerative colitis	N = 48	• **Arm 1:** MEDI7183 low dose, 21mg SC • **Arm 2:** MEDI7183 medium dose, 70mg SC • **Arm 3:** MEDI7183 high dose, 210mg SC • **Arm 4**: Matching Placebo, SC	• Remission at week 8 (Mayo Score)	• FPD: Q4 13 • LPD: Q2 15 • Est. topline results: Q4 15
Anti-IL-23 mAb MEDI2070	**Phase II** **NCT01714726** Partnered	Patients with moderate to severe Crohn's disease	N = 121	• **Arm 1:** MEDI2070, 700mg IV (210mg 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	• FPD: Q1 13 • LPD: Q1 14 • Topline results: Q2 14
	Phase II **NCT02574637** Partnered	Patients with moderate to severe Crohn's disease	N = 342	• **Arm 1:** MEDI2070 High dose • **Arm 2:** MEDI2070 High-Med dose • **Arm 3:** MEDI2070 Low-Med dose • **Arm 4:** MEDI2070 Low dose • **Arm 5:** Placebo	• The primary endpoint is Crohn's Disease Activity Index (CDAI) clinical remission at Week 8, defined by a CDAI score of <150.	• FPD: H1 16 • LPD: 2019 • Topline results: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Other biologics

Autoimmunity

Compound	Study phase	Patient population	Number of patients	Design	Endpoints	Status
Anti-CD19 mAb (MEDI-551)	**Phase II/III** **NCT02200770**	Adults with Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders (NMO/NMOSD)	N = 212 (est.)	• **Arm 1:** MEDI-551500mg IV • **Arm 2:** placebo IV • Open-label extension 300mg Global study 26 Countries	• **Primary:** Time to attack • **Secondary:** Attack rate, safety and tolerability	• FPD: Q1 15 • LPD: 2017 • Est. topline results: 2018
Anti-CD40L (MEDI4920)	**Phase I** **NCT02151110**	Healthy adults	N = 56	• **Arm 1**: 3 mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose • **Arm 2**: 10 mg MEDI4920 (n = 2) or placebo (n = 1) as a single IV dose • **Arm 3**: 30 mg MEDI4920 (n = 3) or placebo (n = 2) as a single IV dose • **Arm 4**: 100 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose • **Arm 5**: 300 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose • **Arm 6**: 1000 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose • **Arm 7**: 2000 mg MEDI4920 (n = 8) or placebo (n = 2) as a single IV dose	• Safety, tolerability, and pharmacokinetics, anti-drug antibody, inhibition of T-cell dependent antibody response	• FPD: Q2 14 • LPD: Q4 15 • Topline results: H1 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Other biologics

Cardiovascular & metabolic disease

Compound	Study phase	Patient population	Number of patients	Design	Endpoints	Status
rhLCAT MEDI6012	**Phase IIa** **NCT02601560**	Adults with stable coronary artery disease and low HDL	N = 56	• SAD in stable coronary artery disease (CAD) patients	• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, immunogenicity and physical examination • Changes in baseline adjusted post dose HDL-C	• FPD: Q4 15 • LPD: H1 16 • Est. topline results: H1 16
rhLCAT MEDI6012	**Phase I** **NCT01554800**	Adults with stable coronary artery disease and low HDL	N = 16	• SAD IV	• Safety • Changes in total HDL • Change in Cholestryl Ester	• Completed by Alphacore
rh-Factor II MEDI8111	**Phase I** **NCT01958645**	Healthy male subjects	N = 12	• SAD IV administration UK study site	• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, immunogenicity and physical examination	• FPD: Q4 13 • LPD: Q4 14 • Completed: Q4 14
GLP-1-Glu MEDI0382	**Phase I** **NCT02394314**	Healthy male subjects	N = 64	• SAD SC administration Germany	• Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination	• FPD: Q1 15 • LPD: Q4 15 • Topline results: Q4 15
MEDI4166	**Phase I** **NCT02524782**	Adults with T2DM	N =124	SAD/MAD SC administration	Part A • Safety/tolerability following SC dosing of 4166 Part B • Characterize the effect of multiple-ascending SC doses on glucose metabolism following an MMTT as measured by glucose AUC • Characterize the effect of multiple-ascending SC doses on LDL-c levels	• FPD: Q4 15 • LPD: H2 16 • Est. topline results: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Durvalumab (MEDI4736; PD-L1 mAb) + *Iressa* (gefitinib)

Non-small cell lung cancer (NSCLC)

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02088112**	NSCLC (Escalation phase) EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase)	N = 36	**Escalation phase** Standard 3+3 design with 28 days DLT period • Gefitinib (QD) + MEDI4736 IV **Expansion phase** • Gefitinib (QD) + MEDI4736 IV recommended dose Global study – 3 countries	• Safety • Optimal biologic dose for the combination • Secondary endpoints include tumour response (CR, PR, SD, PD), Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics	• FPD: Q2 14 • LPD: Q2 15 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Other biologics

Immuno-oncology

Compound	Study phase	Patient population	Number of patients	Design	Endpoints	Status
PD-L1 (durvalumab, MEDI4736)	**Phase I/II** **NCT01693562**	Solid tumours	N = 1,038	• **Dose Escalation:** 5 cohorts at Q2W and 1 cohort at Q3W • **Dose Expansion:** 16 tumour type cohorts at the Q2W MTD defined during dose escalation; one cohort at 20mg Q4W Global study – 8 countries	• Safety • Optimal biologic dose • Secondary endpoints include PK, immunogenicity and antitumour activity	• FPD: Q3 12 • LPD: Q4 15 • Est. topline results: H2 16
PD-L1, azacitidine (MEDI4736, Vidaza)	**Phase I** **NCT02117219**	Myelodysplastic syndrome	N = 41	Dose-escalation and dose-expansion study • **Arm 1:** MEDI4736 IV Global study – 4 countries	• Safety and tolerability of monotherapy and combination • Secondary endpoints include duration of response, progression free survival and overall survival	• FPD: Q2 14 • LPD: Q2 15 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

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

Melanoma

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I/II **NCT02027961**	Metastatic or unresectable melanoma BRAF mutation+ (Cohort A) BRAF wild type (Cohorts B&C)	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	• FPD: Q1 14 • LPD: Q2 15 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Durvalumab (MEDI4736; PD-L1 mAb) + tremelimumab (CTLA-4 mAb)

Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase Ib/II **NCT02340975**	Gastric or GEJ adenocarcinoma	N = 174	• **Arm A:** durvalumab + tremelimumab 2L • **Arm B:** durvalumab 2L • **Arm C:** tremelimumab 2L • **Arm D:** durvalumab + tremelimumab 3L US and ROW study centres	• Safety & tolerability, ORR, PFS • Secondary endpoints include DCR, OS, DoR, PD-L1 Expression	• FPD: Q2 15 • LPD: H1 16 • Est. topline results: 2017
Phase Ib/II **NCT02519348**	Hepatocellular Carcinoma	N = 129	• **Arm A:** durvalumab + tremelimumab • **Arm B:** durvalumab 2L • **Arm C:** tremelimumab 2L	• Safety & tolerability, ORR, PFS • Secondary endpoints include DCR, OS, DoR, PD-L1 Expression	• FPD: Q4 15 • LPD: 2018 • Est. topline results: 2018
Phase Ib **NCT02000947**	NSCLC (Immunotx naïve and Immunotx pretreated patient cohorts)	N = 388	• **Dose Escalation:** minimum 5 cohorts exploring various treme Q4W and MEDI4736 IV Q4W dose combinations, higher dose levels and alternate Q2 schedule added with amendment • **Dose Expansion:** MTD for the combination in escalation to be explored in expansion North American study centres, exploration of ex-US countries for expansion into EU and ROW	• Safety • Optimal biologic dose for the combination • Secondary endpoints include Antitumour activity, PK and immunogenicity	• FPD: Q4 13 • LPD: H2 16 • Est. topline results: 2018
Phase I **NCT02261220**	Solid tumours (Basket study)	N = 392	• **Dose Exploration:** 2 cohorts exploring various Q4W treme and MEDI4736 dose combinations and 2 cohorts exploring various Q2W treme and MEDI4736 dose combinations • **Dose Expansion:** MTD for the combination in escalation to be explored in expansion cohorts specific for each of 7 tumour types North American study centres	• Safety & tolerability • Optimal biologic dose for the combination • Secondary endpoints include Antitumour activity, PK/PD and immunogenicity	• FPD: Q4 14 • LPD: H2 16 • Est. topline results: 2017
Phase I **NCT02262741**	SCCHN	N = 69	• **Arm A:** treatment-naïve, PD-L1+, combo • **Arm B:** treatment-naïve, PD-L1-, combo • **Arm C:** PD1/PDL1 refractory, combo North American study centres	• Safety & tolerability • Secondary endpoints include OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers	• FPD: Q4 14 • LPD: H1 16 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI0562 (OX40 mAb)

Advanced malignancies

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02318394**	Advanced malignancies	N = 50	**Dose-escalation phase** • MEDI0562 IV **Dose-expansion phase** • MEDI0562 IV recommended dose • US-only study centres	• Safety • Determination of MTD • Secondary endpoints include preliminary antitumour activity, pharmacokinetics, biomarker activity, and immunogenicity	• FPD: Q1 15 • LPD: H2 16 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI6383 (OX40 fusion protein) + durvalumab (MEDI4736; PD-L1 mAb)

Advanced malignancies

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02221960**	Advanced malignancies	N = 212	**Dose-escalation phase** • MEDI6383 IV • MEDI6383 IV + MEDI4736 IV **Dose—expansion phase** • MEDI6383 IV recommended dose • MEDI6383 IV + MEDI4736 IV recommended dose US-only study centres	• Safety • Determination of MTD • Secondary endpoints include preliminary antitumour activity, pharmacokinetics, Biomarker activity, and immunogenicity	• FPD: Q3 14 • LPD: H2 16 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI0680 (PD-1 mAb) + durvalumab (MEDI4736)

Advanced malignancies

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02118337**	Advanced malignancies	N = 150	**Dose-escalation phase** • MEDI4736 IV + MEDI0680 IV **Dose-expansion phase at selected dose from dose-escalation phase** • MEDI4736 IV + MEDI0680 IV recommended dose	• Safety • Determination of MTD • Secondary endpoints include tumour response such as objective response rate, disease control rate, progression-free survival, duration of response, overall survival, immunogenicity, pharmacokinetics, pharmacodynamics	• FPD: Q2 14 • LPD: 2017 • Est. topline results: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI9447 (CD73 mAb) + Durvalumab (MEDI4736; PD-L1 mAb)

Advanced malignancies

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02503774**	Advanced malignancies	N = 132	**Dose-escalation phase** • MEDI9447 IV • MEDI9447 IV + Durvalumab IV **Dose—expansion phase** • MEDI9447 IV recommended dose • MEDI9447 IV recommended dose + Durvalumab IV US and Australian study centres	• Safety • Determination of MTD • Secondary endpoints include PK/PD, preliminary antitumour activity, pharmacokinetics, Pharmacodynamics, and immunogenicity	• FPD: Q3 15 • LPD: 2018 • Est. topline results: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI1873 (GITR agonist)

Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02583165**	Adult subjects with select advanced solid tumours	N = 42	**Dose-escalation phase** • MEDI1873 IV US study centres	• Safety • Determination of MTD • Secondary endpoints include PK/PD, preliminary antitumour activity, pharmacokinetics, Pharmacodynamics, and immunogenicity	• FPD: Q4 15 • LPD: H2 16 • Est. topline results: 2019

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI9197 (TLR7/8 agonist)

Solid tumours

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02556463**	Advanced solid tumour malignancies readily accessible for injection	N = 45	**Dose-escalation phase** • MEDI9197 IT US study centres- Ex US under evaluation	• Safety • Determination of MTD • Secondary endpoints include: – Objective response, disease control and duration of response . – Intratumoural and systemic PK and PD profiles/relationships	• FPD: Q4 15 • LPD: 2017 • Est. topline results: 2018

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI4276 (HER2 ADC mAb)

Advanced malignancies

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02576548**	Advanced HER2+ metastatic breast and gastric cancer	Dose escalation N = 21-36 Dose expansion N = 80	• First –time-in-human Phase 1, multicenter, open –label, single-arm, dose-escalation, and dose expansion study for adult subjects	• Primary: Safety • Secondary endpoints include antitumour activity, overall response, disease control, PFS, OS and change from baseline tumour size	• FPD: Q4 15 • LPD: 2017 • Est. topline results: 2017

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI-551 (CD19 mAb)

Haematological malignancies

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase II **NCT01453205**	Adults with relapsed or refractory B-cell diffuse large B-cell lymphoma (DLBCL)	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)	• FPD: Q1 12 • LPD: H1 16 • Est. topline results: 2018
Phase I **NCT01957579**	Adults with relapsed or refractory B-cell malignancies	N = 18	• Dose-escalation study IV Conducted in Japan	• MTD and efficacy	• FPD: Q2 11 • LPD: Q3 15 • Topline results: Q3 15 (completed)

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Other biologics

Solid tumours

Compound	Study phase	Patient population	Number of patients	Design	Endpoints	Status
Anti-IGF ligand mAb (MEDI-573)	**Phase I/II** **NCT01446159**	Patients with HR+ HER2-, 1L, metastatic breast cancer taking aromatase inhibitors	N = 176	• **Arm 1:** MEDI-573 IV and Aromatase Inhibitor • **Arm 2:** Aromatase Inhibitor alone Open label study	• Progression Free Survival • Retrospective evaluation of predictive biomarker +ve subgroups	• FPD: Q2 12 • LPD: Q2 13 • Est. topline results: 2017
Anti-Ang2 mAb (MEDI3617)	**Phase I** **NCT01248949**	Solid tumours and ovarian cancer	N = 25	• MEDI3617 Dose Escalation	• Safety and tolerability	• FPD: Q4 10 • LPD: Q2 15 • Topline results: Q3 15 (completed)
			N = 16	• MEDI3617 + bevacizumab dose escalation, administered Q3W, IV (US only)		
			N = 13	• MEDI3617 + paclitaxel dose escalation, IV (US only)		
			N = 7	• MEDI3617 + carboplatin + paclitaxel dose escalation, IV (US only)		
			N = 27	• MEDI3617 + bevacizumab dose escalation, administered Q2W , IV (US only)		
			N = 17	• MEDI3617 single-agent expansion in ovarian cancer patients, IV (US only)		
			N = 15	• MEDI3617 + bevacizumab dose expansion in recurrent malignant glioma • US-only study centres		

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Other biologics

Solid tumours

Compound	Study phase	Patient population	Number of patients	Design	Endpoints	Status
Anti-CEA BiTE mAb (MEDI-565)	**Phase I** **NCT01284231** Partnered	Adults with gastrointestinal (GI) adenocarcinoma with no available standard or curative treatments. Refractory pancreatic, colorectal and gastro-esophageal cancers	N = 51 max N = 60 max, 20 in each cohort	• Dose-escalation (3+3), IV • Dose expansion study, IV	• MTD and safety profile	• FPD: Q1 11 • LPD Q3 14 • Topline results: Q1 15 completed
Anti-DLL4 mAb (MEDI0639)	**Phase I** **NCT01577745**	Adults with advanced solid tumours including SCLC	N = up to 28	• Dose-escalation study (3+3); IV	• MTD and safety profile	• FPD: Q2 12 • LPD: Q2 15 • Est. topline results: H2 16

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Other biologics

Infections

Compound	Study phase	Patient population	Number of patients	Design	Endpoints	Status
Anti-Staph AT (MEDI4893)	**Phase II** **EudraCT 2014-001097-34**	Intubated ICU	N = 462	• Placebo-controlled, single-dose, dose-ranging • Route of administration: intravenous	• Efficacy and Safety	• FPD: Q4 14 • LPD: 2017 • Est. topline results: 2018
RSV sF+GLA-SE (MEDI7510	**Phase IIb** **NCT02508194**	Adults ≥ 60 yrs	N = 1900	• Randomized, Double-blind Study • Route of administration: intramuscular	• Efficacy	• FPD: Q4 15 • LPD: H1 16 • Est topline results: H2 16
	Phase Ib **NCT02289820**		N = 264	• Double blind, randomized, placebo and active controlled cohort escalation study • Route of administration: intramuscular	• Safety and tolerability • Humoral and cell-mediated immune responses	• FPD: Q1 15 • LPD: Q1 15 • Topline results: Q2 15
	Phase Ia **NCT02115815**		N = 144	• Double blind, randomized, placebo and active controlled cohort escalation study • Route of administration: intramuscular	• Safety and tolerability • Humoral and cell-mediated immune responses	• FPD: Q2 14 • LPD: Q2 14 • Topline results: Q4 14
Anti-RSV mAb-YTE (MEDI8897)	**Phase Ib/IIa** **NCT02290340**	32-35 WK GA infants	N = 89	• Randomized, Double-blind, Placebo-controlled, Dose-escalation Study • Route of administration: IM	• Evaluate Safety, Tolerability, PK and ADA	• FPD: Q1 15 • LPD: Q3 15 • Topline results: Q4 15
	Phase Ia **NCT02114268**	Healthy adults	N = 136	• Randomized, Double-blind, Placebo-controlled, Dose-escalation Study • Route of administration: IV and IM	• Evaluate Safety, Tolerability, PK and ADA	• FPD: Q2 14 • LPD: Q2 14 • Topline results: Q4 14
Anti-influenza A mAb (MEDI8852)	**Phase Ib/IIa** **NCT02603952**	Adults	N = 160	• Randomized, Partial Double-blind, Single Dose, Active-controlled, Dose Ranging Study • Route of administration: intravenous	• Evaluate Safety in Adults with Acute, Uncomplicated Influenza	• FPD: Q4 15 • LPD: H1 16 • Est. topline results: H1 16
	Phase I **NCT02350751**	Healthy adults	N = 40	• Double-blind, Single-dose, Placebo-controlled, Dose-escalation Study • Route of administration: intravenous	• Evaluate the Safety and Pharmacokinetics	• FPD: Q1 15 • LPD: Q1 15 • Topline results: Q2 15
Anti-Pseudomonas a. mAb (MEDI3902)	**Phase I** **NCT02255760**	Healthy adults	N = 56	• Randomized, Double-blind, Placebo-Controlled, Dose-Escalation Study • Route of administration: intravenous	• Evaluate the Safety, Tolerability, and Pharmacokinetics	• FPD: Q3 14 • LPD: Q1 15 • Topline results: Q2 15

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

Vaccine biologics

Influenza vaccines

Compound	Study phase	Patient population	Number of patients	Design	Endpoints	Status
MEDI3250 ***FluMist***	**Phase III** **NCT02269488**	Children 2 to 6 years of age	N = 100	• Open-label • Route of administration: intranasal	• Safety and tolerability	• FPD: Q4 14 • LPD: Q1 15 • Topline results: Q1 15 (completed)
MEDI3250 ***FluMist Quadrivalent***	**Phase III** **NCT02269475**	Children 7 through 18 years of age	N = 1,008	• Randomize, double-blind placebo-controlled • Route of administration: intranasal	• Efficacy assessed by incidence of laboratory-confirmed influenza-like illness in the two treatment arms • Safety and tolerability	• FPD: Q4 14 • LPD: Q4 14 • Topline results: Q2 15 (completed)

Lifecycle management
Late-stage development
Early development - IMED
Early development - MedImmune

MEDI1814 (amyloid beta mAb)

Alzheimer's disease

Study phase	Patient population	Number of patients	Design	Endpoints	Status
Phase I **NCT02036645**	Alzheimer's disease & healthy elderly	N = 121	• SAD & MAD • Up to 10 iv cohorts are planned vs placebo • 2 SC cohorts are planned vs placebo US only	• Safety, tolerability	• FPD: Q2 14 • LPD: H2 16 • Est. topline results: H2 16

Clinical Trials Appendix
Q4 2015 Update

AstraZeneca
What science can do