

Clinical Trials Appendix

Q2 2015 Results Update

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 30 June 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 Q1 2015 update

New to Phase I	New to Phase II	New to Pivotal Study	New to Registration
<p>Additional indications durvalumab[#]+MEDI6383 PD-L1+OX40 solid tumours</p>	<p>Additional indications durvalumab[#]+tremelimumab PD-L1+CTLA-4 gastric cancer PT010 LABA/LAMA/ICS asthma</p>	<p>NMEs anifrolumab^{#1} IFNαR SLE PT010¹ LABA/LAMA/ICS COPD</p> <p>Additional indications AZD9291+durvalumab[#] durvalumab[#]+tremelimumab CONDOR[†] PD-L1+CTLA-4 2L SCCHN</p>	<p>NMEs CAZ AVI[#] serious infections AZD9291 [US, EU] EGFR EGFRm T790M NSCLC 2L+</p>
Removed from Phase I	Removed from Phase II	Removed from Phase III	Removed from Registration
	<p>NMEs tenapanor (AZD1722)[#] NHE3 ESRD-Pi/CKD with T2DM</p>		<p>LCM Nexium [JP] severe refractory oesphagitis² Iressa [US] EGFR EGFRm NSCLC³</p>

[#] Partnered; [†] Registrational Phase II/III trial

¹ FPD July 2015; ² Submission withdrawn Q2 2015; ³ FDA approved July 2015



Q2 New Molecular Entity (NME)[†] Pipeline

■ RIA
 ■ CVMD
 ■ Oncology
 ■ Infection, Neuroscience, Gastrointestinal

Phase I 31 New Molecular Entities		Phase II 25 New Molecular Entities		Phase III 11 New Molecular Entities		Applications Under Review 4 New Molecular Entities	
Small molecule	Large molecule	Small molecule	Large molecule	Small molecule	Large molecule	Small molecule	Large molecule
AZD1419# TLR9 asthma	CD40L-Tn3 Primary Sjogrens	abediterol (AZD0654) LABA asthma, COPD	AZD8412# Inhaled B1FNa5hma, COPD	PT010 LABA/LAMA/ICS COPD	anifrolumab# IFN α SLE	lesinurad URAT-1 gout	
AZD7594 Inhaled SGRM asthma, COPD	MEDI5877# B7RP1 SLE	AZD7624 Inhaled p38 inhibitor COPD	mavrilimumab# GM-CSFR rheumatoid arthritis	PT003 PINNACLE LABA/LAMA COPD	benralizumab# IL-5R severe asthma	AZD9291 AURA 2,3 EGFRm T790M NSCLC >2L	
AZD7986 DPP1 COPD	MEDI7836 IL-13 asthma	RDEA3170 URAT-1/SURI hyperuricemia, gout	MEDI2070# IL-23 Crohns	roxadustat# HIFPH anaemia CKD/ESRD	brodalumab# IL-17R psoriasis	cediranib VEGF PSR ovarian	
AZD8999 MABA asthma, COPD	MEDI0382 GLP-1/gliucagon diabetes, obesity	AZD4901 POCS	MEDI-551# CD19 neuro myelitis optica	selumetinib# SELECT-1 MEK 2L KRAS+ NSCLC	tralokinumab IL-13 severe asthma	CAZ AV# RECLAIM BLI/cephalosporin SBI	
AZD3758 EGFR NSCLC	MEDI0012 LGAT ACS	AZD1775# Wee-1 ovarian	abilimumab (MEDI7183)# α 4 β 7 Crohns, ulcerative colitis		durvalumab (MEDI4636)# ATLANTIC [†]		
AZD6312# androgen receptor prostate	MEDI0111 Rh-FactorII trauma, bleeding	AZD0014 mTOR 1/2 solid tumours	MEDI992# TSLP asthma		mosetumomab# CD22 HCL		
AZD6738 ATR CLL, H&N	MEDI062# hOX40 solid tumours	AZD4547 FGFR solid tumours	sifalimumab# INF α SLE		tremetimumab [†] DETERMINE CTLA-4 mesothelioma		
AZD0186 PI3K β solid tumours	MEDI0639# DLL-4 solid tumours	AZD5363# AKT breast cancer	MEDI-551# CD19 CLL, DLBCL				
AZD8835 PI3K α solid tumours	MEDI0680 PD-1 solid tumours	savolitinib (AZD6094)# MET pRCC	MEDI-573# IGF metastatic breast cancer				
AZD9150# STAT3 haems & solids	MEDI3617# ANG-2 solid tumours	AZD3241 MPO Multiple System Atrophy	MEDI4893 staph alpha toxin SSI				
AZD9496 SERD ER+ breast	MEDI-565# CEA BITE GI tumours	AZD3293# β -secretase Alzheimers	MEDI8897# RSV passive prophylaxis				
ATM AV# BLI SBI	MEDI8383# Ox40 FP solid tumours	AZD5213 H3R neuropathic pain					
AZD1008 NMDA suicidal ideation	MEDI468# mOx40 solid tumours	AZD647 oxazolidinone TB					
	MEDI1814 amyloid β Alzheimers	CXL# BLI/cephalosporin MRSA					
	MEDI3902 Psl/PcrV pseudomonas						
	MEDI-550 pandemic influenza virus vaccine						
	MEDI7510 sIF+GLA-SE RSV prevention						
	MEDI8852 influenza A treatment						

[†] 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; [†] Registrational Phase II/III study
 Note: PT010 COPD and anifrolumab SLE are Q3 2015 Phase III starts



Q2 Lifecycle Management (LCM)[†] Pipeline

■ RIA
 ■ CVMD
 ■ Oncology
 ■ Infection, Neuroscience, Gastrointestinal

Phase I 1 Project		Phase II 8 Projects		Phase III 28 Projects		Applications Under Review 3 Projects	
Small molecule	Large molecule	Small molecule	Large molecule	Small molecule	Large molecule	Small molecule	Large molecule
	durvalumab (MED14636)# PD-L1 solid tumours	PT010 LABA/LAMA/ICS asthma	tralokinumab IL-13 IFF	Symbicort BAI asthma/COPD	Faslodex FALCON 1L advanced breast cancer	benralizumab# IL-5R COPD	Brintita/Brintique PEGASUS prior MI outcomes
		Epanova+Farxiga/Forxiga NASH	tralokinumab IL-13 atopic dermatitis	Symbicort SYGMA as needed in mild asthma	Lynparza GOLD 2L gastric cancer	brodalumab# IL-17R psoriatic arthritis	saxa+dapa FDC diabetes
		Lynparza prostate cancer	durvalumab (MED14636)# PD-L1 solid tumours	Brintita/Brintique EUCLID RAD outcomes	Lynparza OlympiAD gBRCA metastatic breast	durvalumab (MED14636)# PACIFIC PD-L1 NSCLC Stage3	CAZ AVI# IMPROVE HAP/VAP
		selumetinib# MEK2L KRAS- NSCLC	moxetumomab# CD22 pALL	Brintita/Brintique HESTIA paed w/ stroke cell	Lynparza POLO pancreatic cancer	durvalumab (MED14636)# HAWK† PD-L1 2L SOCHN	

Oncology Combinations

Phase I 12 Projects	Phase II 1 Project	Phase III 2 Projects
AZD9291+durvalumab (MED14636)#selumetinib#AZD6094# TATTON	durvalumab (MED14636)#+tremelimumab PD-L1+CTLA-4 gastric cancer	durvalumab (MED14636)#+tremelimumab ARCTIC
durvalumab (MED14636)# sequencing PD-L1 after EGFR/MEK/CTLA-4 NSCLC		durvalumab (MED14636)#+tremelimumab CONDOR†
durvalumab (MED14636)#+dabrafenib+trametinib PD-L1+BRAF+MEK melanoma		
durvalumab (MED14636)#+tressa PD-L1+EGFR NSCLC		
durvalumab (MED14636)#+MEDI0680 PD-L1+PD-1 solid tumours		
durvalumab (MED14636)#+MEDI638# PD-L1+Ox40 agonist solid tumours		
durvalumab (MED14636)#+MEDI646# PD-L1+mOx40 solid tumours		
durvalumab (MED14636)#+tremelimumab PD-L1+CTLA-4 solid tumours		
MEDI-551#+MEDI0680 CD19+PD-1 haems		
MEDI-551#+rituximab PD-L1+CD20 haems		
MEDI646#+rituximab mOX40+CD20 solid tumours		
MEDI646#+tremelimumab mOX40+CTLA-4 solid tumours		

Brintita/Brintique SOCRATES stroke outcomes	Lynparza SOLO-1 1L BRCAm ovarian
Brintita/Brintique THEMIS diabetes & CAD outcomes	Lynparza SOLO-2 >2L BRCAm PSR ovarian
Bydureon weekly suspension	Lynparza SOLO-3 BRCAm PSR ovarian
Bydureon EXSCEL outcomes	Lynparza OlympiA gBRCA adjuvant TNBC
Epanova STRENGTH outcomes	selumetinib# ASTRA MEK2L differentiated thyroid
Farxiga/Forxiga Type 1 diabetes	linaclotide# (CN only) IBS-c
Farxiga/Forxiga DECLARE outcomes	Nexium (CN only) stress ulcer prophylaxis
AZD9291 FLAURA EGFR 1L adv. EGFRm NSCLC	
Capretea differentiated thyroid cancer	

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

Partnered; † Registrational Phase III/III study; ‡ MedImmune-sponsored study in collaboration with Novartis



2015-2016: 14-16 NME & LCM submissions

LCM submission opportunities				MEDI4736 + tremelimumab 2L SCCHN
			Faslodex 1L metastatic breast cancer	MEDI4736 2L SCCHN
			Brilinta stroke	Lynparza BRCAm metastatic breast cancer
		saxa/dapa FDC type 2 diabetes ✓	brodalumab* psoriatic arthritis	Lynparza BRCAm PSR ovarian cancer (SOLO-2)
	Brilinta prior MI ✓	Bydureon autoinjector	lesinurad FDC gout	Caprelsa differentiated thyroid cancer
NME submission opportunities	CAZ AVI (CEPH/BLI) serious infections ✓	cediranib (VEGFR) ovarian cancer (EU) ✓		AZD6094 MET (cMET) papillary renal cell carcinoma
	brodalumab* (IL-17R) psoriasis	selumetinib (MEK) uveal melanoma ✗	roxadustat (HIF) CKD / ESRD (China)	tremelimumab (CTLA-4) mesothelioma
	PT003 (LAMA/LABA) COPD	AZD9291 (EGFR T790) 2L NSCLC ✓	benralizumab (IL-5R) severe asthma	MEDI4736 (PD-L1) 3L NSCLC
2015			2016	

*Amgen has announced that it has terminated development of brodalumab; AstraZeneca has announced it will confirm its decision on the future development of brodalumab



Immuno-oncology

Major trials I

Tumour type	Line of therapy	Treme (CTLA-4 mAb)	Combo durva + treme	Durva (PD-L1 mAb)	Combo durva + OX40	OX40	Combo treme + OX40
Mesothelioma	Second line	DETERMINE Phase II					
NSCLC	Adjuvant			ADJUVANT Phase III			
	Stage III un-resectable			PACIFIC Phase III			
	First line		MYSTIC Phase III NEPTUNE Phase III	MYSTIC Phase III + CTx Phase III + Iressa Phase III			
	EGFRm+						
	Second line T790M			CAURAL + AZD9291 Phase III			
	Third line PD-L1+	ARCTIC Phase III	ARCTIC Phase III	ARCTIC Phase III ATLANTIC Ph II/single arm			



Immuno-oncology

Major trials II

Tumour type	Line of therapy	Treme (CTLA-4 mAb)	Combo durva + treme	Durva (PD-L1 mAb)	Combo durva + OX40	OX40	Combo treme + OX40
SCCHN	Second line PD-L1- PD-L1+	CONDOR Phase II	EAGLE Phase III CONDOR Phase II	EAGLE Phase III CONDOR HAWK Phase II			
Gastric	Second/third line	NAME TBD Phase II	NAME TBD Phase II	NAME TBD Phase II			
Pancreas	Second line		NAME TBD Phase II				
Bladder	First line		NAME TBD Phase III	NAME TBD Phase III			
Melanoma	-			+ BRAFi, MEKi Phase I/II			
Other advanced cancer	-			+ MEDI0680 (PD-1) Phase I	MEDI6469 (murine) Phase I/II	MEDI0562 (mAb) MEDI6383 (fusion protein) Phase I	MEDI6469 (murine) Phase I/II



Lifecycle management (new uses of existing medicines)



Symbicort (ICS/LABA)

Mild asthma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Patients in need of GINA step 2 treatment	Phase III SYGMA1 NCT02149199	N = 3,750	<ul style="list-style-type: none"> Arm 1: Symbicort Turbuhaler 160/4.5 µg 'as needed' + Placebo Pulmicort Turbuhaler 200 µg bid Arm 2: Pulmicort 200 µg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler 'as needed' Arm 3: terbutaline Turbuhaler 0.4 mg 'as needed' + placebo Pulmicort 200 µg Turbuhaler bid <p>Global study – 19 countries</p>	<ul style="list-style-type: none"> Well controlled asthma weeks Time to first severe asthma exacerbation Time to first moderate or severe asthma exacerbation Average change from baseline in pre-dose FEV1 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: 2017 Est. completion: 2017 Est. topline results: 2017
Patients in need of GINA step 2 treatment	Phase III SYGMA2 NCT02224157	N = 4,114*	<ul style="list-style-type: none"> Arm 1: Symbicort Turbuhaler 160/4.5 µg 'as needed' + Placebo Pulmicort Turbuhaler 200 µg bid Arm 2: Pulmicort 200 µg Turbuhaler bid + terbutaline 0.4 mg Turbuhaler 'as needed' <p>Global study – 25 countries</p>	<ul style="list-style-type: none"> Annual severe asthma exacerbation rate Time to first severe asthma exacerbation Average change from baseline in pre-dose FEV1 Time to study specific asthma related discontinuation 	<ul style="list-style-type: none"> 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.



Eklira/Tudorza (LAMA)

Chronic Obstructive Pulmonary Disease (COPD)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Patients with COPD	Phase IV NCT02375724 Partnered: Menarini	N = 224	<ul style="list-style-type: none"> Arm 1: aclidinium bromide 400 µg Arm 2: Placebo to aclidinium bromide 400 µg Global Study – 5 countries	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: Q3 15 Est. completion: H1 16
Patients with moderate to very severe COPD	Phase IV ASCENT NCT01966107 Partnered: Forest/Actavis	N = 4,000	<ul style="list-style-type: none"> Arm 1: aclidinium bromide 400 µg Arm 2: Placebo to aclidinium bromide 400 µg Global Study – 2 countries	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPD: Q4 13 LPD: Q1 15 Est. completion: 2018
Patients with stable moderate and severe COPD	Phase IV NCT02153489 Partnered: Almirall	N = 30	<ul style="list-style-type: none"> Arm 1: aclidinium bromide 400 µg Arm 2: Placebo to Acclidinium bromide 400 µg Local Study – 1 country	<ul style="list-style-type: none"> 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. 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: Q2 15 Est. completion: Q3 15



Duaklir (LAMA/LABA)

Chronic Obstructive Pulmonary Disease (COPD)

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

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Patients with moderate to COPD	Phase IV ACTIVATE CTs.gov Identifier: In progress CO-FUNDED: Menarini	N = 268	<ul style="list-style-type: none">• Arm 1: aclidinium/formoterol FDC 400/12 µg• Arm 2: Placebo to aclidinium/formoterol FDC 400/12 µg Global Study – 5 Countries	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• FPD: Q2 15• LPD: Q4 15• Estimated completion date: H1 16



Brilinta/Brilique (ADP receptor antagonist)

Cardiovascular

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Patients with prior MI	Phase III PEGASUS NCT01225562	N = 21,000	<ul style="list-style-type: none"> • Arm 1: Ticagrelor 90 mg BiD • Arm 2: Ticagrelor 60 mg BiD • Arm 3: Placebo BiD <i>on a background of ASA</i> Global study – 31 countries	<ul style="list-style-type: none"> • Composite of CV death, non-fatal MI and non-fatal stroke 	<ul style="list-style-type: none"> • FPD: Q4 10 • LPD: Q4 14 • Completion date: Q1 15
Patients with PAD	Phase III EUCLID NCT01732822	N = 13,500	<ul style="list-style-type: none"> • Arm 1: Ticagrelor 90 mg BiD • Arm 2: Clopidogrel 75 mg QD <i>monotherapy trial</i> Global study – 28 countries	<ul style="list-style-type: none"> • Composite of CV death, non-fatal MI and ischemic stroke 	<ul style="list-style-type: none"> • FPD: Q4 12 • LPD: H2 16 • Est. topline results: H2 16
Patients with stroke or TIA	Phase III SOCRATES NCT01994720	N = 13,600	<ul style="list-style-type: none"> • Arm 1: Ticagrelor 90 mg BiD • Arm 2: ASA 100mg/day <i>monotherapy trial</i> Global study – 33 countries	<ul style="list-style-type: none"> • Composite of non-fatal stroke, non-fatal MI and all cause death 	<ul style="list-style-type: none"> • FPD: Q1 14 • LPD: H1 16 • Est. topline results: H1 16
Patients with type 2 diabetes and coronary artery disease without a previous history of MI or stroke	Phase III THEMIS NCT01991795	N = 17,000	<ul style="list-style-type: none"> • Arm 1: Ticagrelor 90 mg BiD • Arm 2: Placebo BiD <i>on a background of ASA if not contra indicated or not tolerated</i> Global study – approx. 40 countries	<ul style="list-style-type: none"> • Composite of CV death, non-fatal MI and non-fatal stroke 	<ul style="list-style-type: none"> • FPD: Q1 14 • LPD: 2017 • Est. topline results: 2017
Japanese healthy volunteers	Phase III (BE) NCT02436577	N = 36	Single dose, Cross-Over <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • BE of ticagrelor Dispersible Tablet vs ticagrelor IR tablet 	<ul style="list-style-type: none"> • FPD: Q2 15 • LPD: Q3 15 • Est. topline results: Q4 15
Caucasian healthy volunteers	Phase III (BE) NCT02400333	N = 36	Single dose, Cross-Over <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • BA/BE of ticagrelor Dispersible Tablet vs ticagrelor IR tablet 	<ul style="list-style-type: none"> • FPD: Q2 15 • LPD: Q3 15 • Est. topline results: Q4 15



Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Severe hyper-triglyceridaemia	Phase III EVOLVE II NCT02009865	N = 162	<ul style="list-style-type: none"> • Arm 1: Epanova 2g QD • Arm 2: Placebo (olive oil) Global study – 7 countries	<ul style="list-style-type: none"> • Change in serum triglycerides over 12 weeks 	<ul style="list-style-type: none"> • FPD: Q4 13 • LPD: Q4 14 • Est. topline results: Q2 15
Patients with hypertriglyceridaemia and high CVD risk	Phase III STRENGTH (CVOT) NCT02104817	N = 13,000	<ul style="list-style-type: none"> • Arm 1: Epanova 4g QD + statin • Arm 2: Placebo (corn oil) + statin Global study – 22 countries	<ul style="list-style-type: none"> • Composite of MACE 	<ul style="list-style-type: none"> • FPD: Q4 14 • Est. topline results: 2019
Healthy male Japanese and Caucasian subjects	Phase I SAD/MAD NCT02209766	N = 18	<ul style="list-style-type: none"> • Arm 1: (Japanese): Epanova 2g vs. Placebo QD • Arm 2: (Japanese): Epanova 4g vs Placebo QD • Arm 3: (Caucasian): Epanova 4g vs Placebo Local study – 1 country	<ul style="list-style-type: none"> • PK of single and multiple doses in healthy male Japanese subjects • Safety/tolerability profile 	<ul style="list-style-type: none"> • FPD: Q3 14 • LPD: Q4 14 • Topline results: Q2 15
Patients with a history of pancreatitis	Phase I NCT02189252	N = 16	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Plasma concentration vs. time curve (AUC0-t) • LPD: Q2 15 • [Time Frame: 0 to 24 hours (AUC0-24)] 	<ul style="list-style-type: none"> • FPD: Q3 14 • LPD: Q2 15 • Est. topline results: Q3 15



Epanova (omega-3 carboxylic acids)

Hypertriglyceridaemia

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Type 2 DiM Liver fat >5.5%	Phase II EFFECT II NCT02279407	N = 80	<ul style="list-style-type: none"> • Arm 1: Epanova 4g QD • Arm 2: Placebo (olive oil) • Arm 3: Epanova 4gm + dapagliflozin 10 mg QD • Arm 4: dapagliflozin 10 mg <p>Local study – 1 country</p>	<ul style="list-style-type: none"> • Reduction in liver fat content (%) at the end of 12 weeks 	<ul style="list-style-type: none"> • FPD: Q1 15 • LPD: Q4 15 • Est. topline results: Q3 15
Pancreatic Exocrine Insufficiency (PEI) in patients with type 2 diabetes	Phase I PRECISE NCT02370537	N = 66	<ul style="list-style-type: none"> • Arm 1: Epanova® 4g single dose • Arm 2: Omacor® 4 g single dose <p>Global study – 6 countries in Europe</p>	<ul style="list-style-type: none"> • Presence of Pancreatic Exocrine Insufficiency (PEI), Pharmacokinetics of Epanova and Omacor following a single oral dose in patients with different degrees of PEI 	<ul style="list-style-type: none"> • FPD: Q1 15 • LPD: Q3 15 • Est. topline results: Q4 15
Healthy volunteers	Phase I Microsphere bioavailability NCT02359045	N = 40 Part A N = 42 Part B	<ul style="list-style-type: none"> • Arm 1: D1400147 4g • Arm 2: D14000136 4g • Arm 3: D14000137 4g • Arm 4: Epanova 4g <p>Local study – 1 country</p>	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • FPD: Q1 15 • LPD: Q3 15 • Est. topline results: Q3 15
Healthy male volunteers	Phase I Japanese food interaction NCT02372344	N = 42	<ul style="list-style-type: none"> • Epanova 4 g X 3 separate occasions (fasting, before meal, and after meal) <p>Local study – 1 country</p>	<ul style="list-style-type: none"> • Effect of food timing (fasting, before meal, and after meal) on pharmacokinetics (AUC, Cmax, AUC0-72) 	<ul style="list-style-type: none"> • FPD: Q1 15 • LPD: Q2 15 • Est. topline results: Q4 15
Japanese patients with hypertriglyceridemia	Phase III Japanese Long-term Safety NCT02463071	N = 375	<ul style="list-style-type: none"> • Epanova 2 g and 4 g vs. Placebo (after meal) daily for 52 weeks <p>Global study – 1 country</p>	<ul style="list-style-type: none"> • Safety in Japanese patients • % change in triglycerides 	<ul style="list-style-type: none"> • FPD: Q2 15 • LPD: 2017 • Est. topline results: 2017



Onglyza (DPP-IV inhibitor)

Type 2 Diabetes

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

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Type 2 diabetes mellitus	Phase III NCT02104804	N = 444	<ul style="list-style-type: none"> Arm 1: Onglyza 5 mg QD +insulin or Onglyza 5 mg QD+ insulin + Met: Placebo QD +insulin or Placebo Arm 2QD + insulin + Met <p>Study in China</p>	<p>Primary:</p> <ul style="list-style-type: none"> Change from baseline in HbA1C at 24 weeks <p>Secondary:</p> <ul style="list-style-type: none"> Change from baseline at 24 weeks in 120-minute postprandial plasma glucose (PPG) in response to a meal tolerance 	<ul style="list-style-type: none"> FPD: Q3 14 LPD: Q4 15 Est. topline results: H2 16
Type 2 diabetes mellitus	Phase III NCT02273050	N = 639	<ul style="list-style-type: none"> Arm 1: Onglyza 5 mg + Met (500 mg with titration) Arm 2: Onglyza 5 mg + Placebo Arm 3: Met (500 mg with titration) + Placebo <p>Study in China</p>	<p>Primary:</p> <ul style="list-style-type: none"> The change in HbA1c from baseline to week 24 (prior to rescue) <p>Secondary</p> <ul style="list-style-type: none"> The proportion of subjects achieving a therapeutic glycaemic response at week 24 (prior to rescue) defined as HbA1c <7.0% 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: H1 16 Est. topline results: 2017



Farxiga/Forxiga (SGLT-2 inhibitor)

Diabetes

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Type 2 diabetes mellitus with high risk for CV event	Phase III/IV DECLARE NCT01730534	N = 17,150	<ul style="list-style-type: none"> • Arm 1: Forxiga 10 mg QD + standard of care therapy QD • Arm 2: Placebo + standard of care therapy for Type 2 Diabetes <p>Global study – 33 countries</p>	<ul style="list-style-type: none"> • Time to first event included in the composite endpoint of CV death, MI or ischemic stroke 	<ul style="list-style-type: none"> • FPD: Q2 13 • LPD: 2019 • Est. topline results: 2019 • Est. completion date: 2019
Japanese patients with type 2 diabetes with inadequate glycemic control on insulin	Phase IV NCT02157298	N = 224	<ul style="list-style-type: none"> • Arm 1: Forxiga 5mg • Arm 2: Placebo <p>Japan study</p>	<ul style="list-style-type: none"> • Change from baseline in HbA1c at week 16 • 1 year LT data 	<ul style="list-style-type: none"> • FPD: Q2 14 • LPD: Q4 15 • Est. topline results: (Short Term part of study) Q3 15 • Est. completion date: H1 16
Asian subjects with type 2 diabetes who have inadequate glycemic control on insulin	Phase III NCT02096705 Partnered: BMS	N = 260	<ul style="list-style-type: none"> • Arm 1: Forxiga 10 mg QD for 24 weeks + background Insulin • Arm 2: Placebo QD for 24 weeks + background Insulin <p>Asian study 3 countries</p>	<ul style="list-style-type: none"> • Change from baseline in HbA1c at week 24 	<ul style="list-style-type: none"> • FPD: Q1 14 • LPD: H1 16 • Est. topline results: H1 16 • Est. completion date: H2 16
Patients with Type 2 diabetes and moderate renal impairment	Phase III NCT02413398	N = 302	<ul style="list-style-type: none"> • Arm 1: Forxiga 10 mg QD for 24 weeks • Arm 2: Placebo 10 mg QD for 24 weeks <p>Global study – 5 countries</p>	<ul style="list-style-type: none"> • Change from baseline in HbA1c at Week 24 	<ul style="list-style-type: none"> • FPD: Q2 15 • LPD: 2017 • Est. topline results: 2017 • Est. completion date: 2017



Farxiga/Forxiga (SGLT-2 inhibitor)

Diabetes

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Type 1 diabetes mellitus	Phase III NCT02268214 Partnered: BMS	N = 768	<ul style="list-style-type: none"> Arm 1: Forxiga 5 mg QD 52 weeks + insulin Arm 2: Forxiga 10 mg QD 52 weeks + insulin Arm 3: Placebo QD 52 weeks + insulin Global study – 17 countries	Primary: <ul style="list-style-type: none"> Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at Week 24 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: 2017 Est. topline results: 2017
Type 1 diabetes mellitus	Phase III NCT02460978 Partnered: BMS	N = 819	<ul style="list-style-type: none"> Arm 1: Forxiga 5 mg QD 52 weeks + insulin Arm 2: Forxiga 10 mg QD 52 weeks + insulin Arm 3: Placebo QD 52 weeks + insulin Global Study-14 countries	Primary: <ul style="list-style-type: none"> Adjusted Mean Change From Baseline in Haemoglobin A1C (HbA1c) at Week 24 	<ul style="list-style-type: none"> FPD: Q3 15 LPD: 2017 Est. topline results: 2017



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

Diabetes

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Type 2 diabetes mellitus	Phase III NCT01619059	N = 280	<ul style="list-style-type: none"> Arm 1: Saxa 5mg + Dapa 10 mg + Met IR Arm 2: Placebo + Dapa 10 mg + Met IR Global study – 9 countries	Primary: <ul style="list-style-type: none"> Mean change from baseline in HbA1C at week 24 Secondary: <ul style="list-style-type: none"> Mean change from baseline in 2h MTT at week 24 	<ul style="list-style-type: none"> FPD: Q4 12 Est. topline results: Q4 14 Completed : Q2 15
Type 2 diabetes mellitus	Phase III NCT01646320	N = 280	<ul style="list-style-type: none"> Arm 1: Dapa 10 mg + Saxa 5 mg + Met IR Arm 2: Placebo + Saxa 5 mg + Met IR Global study – 8 countries	Primary: <ul style="list-style-type: none"> Mean change from baseline in HbA1C at week 24 Secondary: <ul style="list-style-type: none"> Mean change from baseline in FPG at week 24 	<ul style="list-style-type: none"> FPD: Q4 12 Est. topline results: Q3 14 Completed : Q2 15
Type 2 diabetes mellitus	Phase III NCT02284893	N = 420	<ul style="list-style-type: none"> Arm 1: Saxa 5 mg + Dapa 10 mg + Met IR/XR Arm 2: Sitagliptin 100 mg + Met IR/XR Global study – 6 countries	Primary: <ul style="list-style-type: none"> Mean change from baseline in HbA1C at week 24 Secondary: <ul style="list-style-type: none"> The proportion of subjects achieving a therapeutic glycemic response at week 24 defined as HbA1C<7% Mean change in total body weight at Week 24 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: H1 16 Est. topline results: H2 16
Type 2 diabetes mellitus	Phase III NCT02419612	N = 440	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Mean change from baseline in HbA1c at Week 52 Secondary: <ul style="list-style-type: none"> 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%, 	<ul style="list-style-type: none"> FPD: Q3 15 LPD: H2 16 Est. topline results: 2017

*studies performed by BMS



Bydureon (GLP-1 receptor agonist)

Type 2 Diabetes

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Type 2 diabetes	Phase III DURATION-NEO 1 NCT01652716 Partnered	N = 375	<ul style="list-style-type: none">• Arm 1: <i>Bydureon</i> BiD SC (autoinjector)• Arm 2: <i>Bydureon</i> weekly suspension SC (autoinjector) <p>On a background of diet & exercise alone or with stable regimen of oral antidiabetes US only</p>	<ul style="list-style-type: none">• Change in HbA1c from baseline at 28 weeks	<ul style="list-style-type: none">• FPD: Q1 13• Completion: Q3 14
Type 2 diabetes	Phase III DURATION-NEO 2 NCT01652729 Partnered	N = 360	<ul style="list-style-type: none">• Arm 1: Sitagliptin• Arm 2: <i>Bydureon</i> weekly suspension SC (autoinjector)• Arm 3: Placebo <p>On a background of diet & exercise alone or with stable regimen of oral antidiabetes US only</p>	<ul style="list-style-type: none">• Change in HbA1c from baseline at 28 weeks	<ul style="list-style-type: none">• FPD: Q1 13• Completion : Q3 14



Bydureon (GLP-1 receptor agonist)

Type 2 Diabetes

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Type 2 diabetes	Phase IV EXSCEL NCT01144338 Partnered	N = 14,000	<ul style="list-style-type: none"> • Arm 1: <i>Bydureon</i> once weekly 2mg SC • Arm 2: Placebo <p>On a background of standard of care medication, different degree of CV risk</p> <p>Global study</p>	<ul style="list-style-type: none"> • Time to first confirmed CV event in the primary composite CV endpoint (CV death, non-fatal MI, non-fatal stroke) 	<ul style="list-style-type: none"> • FPD: Q2 10 • LPD: Q2 15 • Est. completion: 2018
Type 2 diabetes	Phase III DURATION 7 NCT02229383	N = 440	<ul style="list-style-type: none"> • Arm 1: <i>Bydureon</i> once weekly 2 mg SC + Titrated Basal Insulin • Arm 2: Placebo + Titrated Basal Insulin <p>Double-blind 1:1 randomization Background therapy with or without Metformin</p> <p>Global Study</p>	<ul style="list-style-type: none"> • Change in HbA1c from baseline at 28 weeks 	<ul style="list-style-type: none"> • FPD: Q3 14 • LPD: Q4 15 • Est. completion: 2016
Type 2 diabetes	Phase III DURATION 8 NCT02229396	N = 660	<ul style="list-style-type: none"> • Arm 1: <i>Bydureon</i> once weekly 2 mg SC • Arm 2: Dapagliflozin 10 mg • Arm 3: <i>Bydureon</i> once weekly 2 mg SC + Dapagliflozin 10 mg <p>Double-blind 1:1:1 randomization Background therapy with Metformin 1500 mg/day up to 2 months prior to screening</p> <p>Global Study</p>	<ul style="list-style-type: none"> • Change in HbA1c from baseline at 28 weeks 	<ul style="list-style-type: none"> • FPD: Q3 14 • LPD: Q4 15 • Est. completion: 2016 for 28-week data and 2017 for 52-week data



Faslodex (oestrogen receptor antagonist)

Breast cancer - metastatic

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Postmenopausal women with HR+ locally advanced or metastatic breast cancer, who have not previously been treated with any hormonal therapy (1 st -line)	Phase III FALCON NCT01602380	N ~450	<ul style="list-style-type: none"> Arm 1: Faslodex 500 mg monthly IM + an additional dose on d14 (+ oral placebo) Arm 2: Arimidex 1 mg (+ placebo injection) Global study – 21 countries	<ul style="list-style-type: none"> Progression Free Survival (PFS) Overall Survival is a secondary endpoint 	<ul style="list-style-type: none"> FPD: Q4 12 LPD: Q3 14 Est. topline results: H1 16



Caprelsa (kinase inhibitor)

Thyroid cancer - metastatic

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

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Differentiated thyroid cancer refractory or unsuitable for radioiodine therapy	Phase III NCT01876784	N = 227	<ul style="list-style-type: none">• Arm 1: Vandetanib 300 mg oral dose QD• Arm 2: Placebo Global study – 12 countries	<ul style="list-style-type: none">• Progression Free Survival	<ul style="list-style-type: none">• FPD: Q3 13• LPD: Q4 14• Est. completion date: 2017



Lynparza (PARP inhibitor)

Ovarian cancer and other solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
PSR BRCAm ovarian cancer	Phase III SOLO-2 Partnered NCT01874353	N = 264	<ul style="list-style-type: none"> Arm 1: Lynparza tablets 300 mg BiD as maintenance therapy until progression Arm 2: placebo tablets BiD Global study	<ul style="list-style-type: none"> Progression Free Survival Overall Survival secondary endpoint. 	<ul style="list-style-type: none"> FPD: Q3 13 LPD: Q4 14 Est. topline results: H1 16
1L maintenance BRCAm ovarian cancer	Phase III SOLO-1 Partnered NCT01844986	N = 344	<ul style="list-style-type: none"> Arm 1: Lynparza tablets 300 mg BiD maintenance therapy for 2 years or until disease progression Arm 2: placebo Global study	<ul style="list-style-type: none"> Progression Free Survival Overall Survival secondary endpoint. 	<ul style="list-style-type: none"> FPD: Q3 13 LPD: Q1 15 Est. topline results: H2 16
PSR gBRCAm ovarian cancer 3+ Line	Phase III SOLO-3 NCT02282020	N = 411	<ul style="list-style-type: none"> Arm 1: Lynparza 300 mg BiD to progression Arm 2: Physician's choice (single agent chemotherapy) Global study	<ul style="list-style-type: none"> Progression Free Survival Overall Survival secondary endpoint 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: 2017 Est. topline results: 2018
2L gastric cancer (all patients with a co-primary sub population)	Phase III GOLD NCT01924533	N = 500	<ul style="list-style-type: none"> Arm 1: paclitaxel + Lynparza until progression Arm 2: paclitaxel + placebo Lynparza dose 100mg BiD throughout paclitaxel dose cycle & 300 mg BiD post cycle Asian study	<ul style="list-style-type: none"> Overall Survival 	<ul style="list-style-type: none"> FPD: Q3 13 LPD: Q3 15 Est. topline results: H2 16



Lynparza (PARP inhibitor)

Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
BRCAm metastatic breast cancer	Phase III OlympiAD NCT02000622	N = 310	<ul style="list-style-type: none"> Arm 1: Lynparza 300 mg BiD, continuous to progression Arm 2: Physician's choice: Capecitabine 2500 mg/m² x 14 q 21 Vinorelbine 30 mg/m² d 1, 8 q 21 Eribulin 1.4 mg/m² d 1, 8 q 21 to progression <p>Global study</p>	<ul style="list-style-type: none"> Progression Free Survival Secondary endpoint: Overall Survival 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: Q4 15 Est. topline results: H1 16
BRCAm adjuvant breast cancer	Phase III OlympiA Partnered NCT02032823	N = 1,320	<ul style="list-style-type: none"> Arm 1: Lynparza 300 mg BiD 12 month duration Arm 2: Placebo 12 month duration <p>Global study partnership with BIG and NCI/NRG</p>	<ul style="list-style-type: none"> Invasive Disease Free Survival (IDFS) Secondary endpoint: Distant Disease Free Survival and Overall Survival 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: 2018 Est. topline results: 2020
Pancreas gBRCA	Phase III POLO NCT02184195	N = 145	<ul style="list-style-type: none"> Arm 1: Lynparza tablets 300 mg twice daily as maintenance therapy until progression. Arm 2: placebo tablets BiD <p>Global study</p>	<ul style="list-style-type: none"> Primary endpoint: Progression Free Survival Secondary endpoint: Overall Survival 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: Q4 15 Est. topline results: H1 16
Metastatic castration resistant prostate CA	Phase II NCT01972217	N = 170	<ul style="list-style-type: none"> Arm 1: Lynparza 300mg BiD + Abiraterone Arm 2: Placebo + Abiraterone <p>Global study</p>	<ul style="list-style-type: none"> Radiologic Progression Free Survival 	<ul style="list-style-type: none"> FPD: Q3 14 LPD: Q3 15 Est. topline results: H2 16

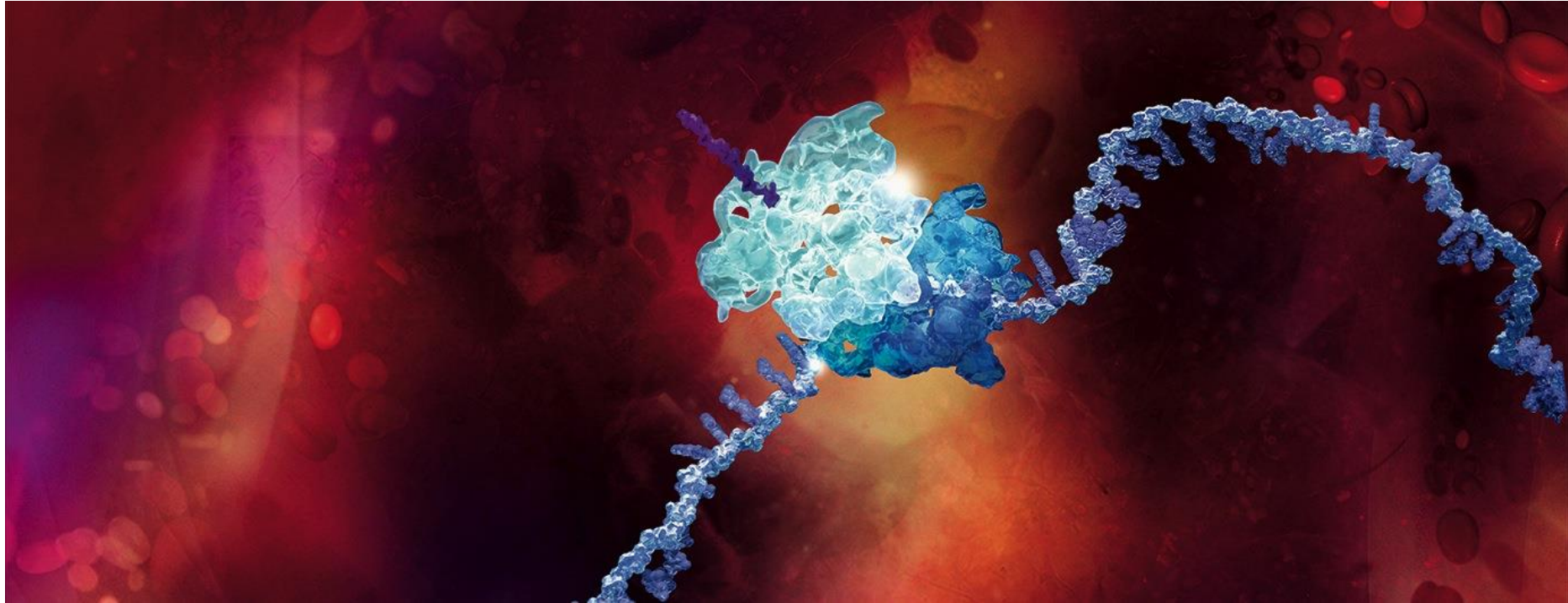


Nexium, Entocort, Linaclotide

Gastrointestinal

Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
<i>Nexium</i>	Refractory RE	Phase III ROSE NCT01669811	N = 280	<ul style="list-style-type: none"> • Arm 1: <i>Nexium</i> 20 mg BiD • Arm 2: <i>Nexium</i> 20 mg QD <p>Japan-only study</p>	<ul style="list-style-type: none"> • Healing of refractory RE 	<ul style="list-style-type: none"> • FPD: Q3 12 • LPD: Q1 14 • Completion date: Q2 14
<i>Nexium</i>	Seriously ill patients (Stress Ulcer Prophylaxis, SUP)	Phase III NCT02157376	N = 300	<ul style="list-style-type: none"> • Arm 1: <i>Nexium</i> 30 min intermittent infusions given for max.14 days • Arm 2: Cimetidine(Tagamet) 30 min bolus infusion + continuous infusion for max. 14 days <p>China-only study</p>	<ul style="list-style-type: none"> • Proportion of patients with upper GI bleeding 	<ul style="list-style-type: none"> • FPD: Q3 14 • LPD: H2 16 • Est. Completion: H2 16
<i>Entocort</i>	Crohn's disease (mild to moderate)	Phase III NCT01514240	N = 110	<ul style="list-style-type: none"> • Arm 1: <i>Entocort</i> 9 mg QD • Arm 2: Mesalazine 1 g TD <p>Japan-only study</p>	<ul style="list-style-type: none"> • Remission defined by a CDAI score of ≤150 	<ul style="list-style-type: none"> • FPD: Q1 12 • LPD: Q2 14 • Completion : Q3 14
<i>Linaclotide</i>	IBS-C	Phase III NCT01880424	N = 800	<ul style="list-style-type: none"> • Arm 1: Linaclotide 290µg QD • Arm 2: placebo <p>Participating countries China, Australia, New Zealand, USA and Canada</p>	<ul style="list-style-type: none"> • 12-week abdominal pain/abdominal discomfort response • 12-week IBS degree of relief response 	<ul style="list-style-type: none"> • FPD: Q3 13 • LPD: Q1 15 • Completion: Q2 15

Late-stage development



Lesinurad (SURI, URAT 1 inhibitor)

Gout

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Gout with inadequate hypouricemic response to allopurinol	Phase III CLEAR 1 NCT01510158	N = 600	<ul style="list-style-type: none"> Arm 1: Placebo Arm 2: lesinurad 200 mg QD Arm 3: lesinurad 400 mg QD All arms: SOC allopurinol QD	<ul style="list-style-type: none"> Proportion of subjects with an sUA level that is < 6.0 mg/dL by Month 6 	<ul style="list-style-type: none"> FPD: Q1 12 LPD: Q3 13 Study complete
Gout with inadequate hypouricemic response to allopurinol	Phase III CLEAR 2 NCT01493531	N = 600	<ul style="list-style-type: none"> Arm 1: Placebo Arm 2: lesinurad 200 mg QD Arm 3: lesinurad 400 mg QD All arms: SOC allopurinol QD	<ul style="list-style-type: none"> Proportion of subjects with an sUA level that is < 6.0 mg/dL by Month 6 	<ul style="list-style-type: none"> FPD: Q4 11 LPD: Q2 13 Study complete
Tophaceous gout	Phase III CRYSTAL NCT01510769	N = 315	<ul style="list-style-type: none"> Arm 1: Placebo Arm 2: lesinurad 200 mg QD Arm 3: lesinurad 400 mg QD All arms: febuxostat 80 mg QD	<ul style="list-style-type: none"> Proportion of subjects with an sUA level that is < 5.0 mg/dL by Month 6 	<ul style="list-style-type: none"> FPD: Q1 12 LPD: Q2 13 Study complete
Gout with intolerance or contraindication to a xanthine oxidase inhibitor	Phase III LIGHT NCT01508702	N = 200	<ul style="list-style-type: none"> Arm 1: Placebo Arm 2: lesinurad 400 mg QD 	<ul style="list-style-type: none"> Proportion of subjects with an sUA level that is < 6.0 mg/dL at Month 6 	<ul style="list-style-type: none"> FPD: Q1 12 LPD: Q2 13 Study complete
Gout previously enrolled LIGHT study	Phase III LIGHT Ext NCT01650246	N = 143	All arms: open-label lesinurad 400 mg QD	<ul style="list-style-type: none"> Assess the long-term efficacy and safety of lesinurad monotherapy. 	<ul style="list-style-type: none"> FPD: Q4 12 LPD: Q1 14 Study complete
Gout previously enrolled in studies CLEAR 1 & 2	Phase III CLEAR Ext NCT01808131	N ≤ 200	<ul style="list-style-type: none"> Arm 1: lesinurad 200 mg QD Arm 2: lesinurad 400 mg QD All arms: SOC allopurinol QD	<ul style="list-style-type: none"> Assess the long-term efficacy and safety of lesinurad in combination with allopurinol. 	<ul style="list-style-type: none"> FPD: Q1 13 LPD: Q2 14 Study ongoing
Gout previously enrolled in CRYSTAL study	Phase III CRYSTAL Ext NCT01808144	N ≤ 315	<ul style="list-style-type: none"> Arm 1: lesinurad 200 mg QD Arm 2: lesinurad 400 mg QD All arms: febuxostat 80 mg QD	<ul style="list-style-type: none"> Assess the long-term efficacy and safety of lesinurad in combination with febuxostat. 	<ul style="list-style-type: none"> FPD: Q1 13 LPD: Q2 14 Study ongoing



Brodalumab (IL-17R mAb)

Psoriasis & psoriatic arthritis

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Moderate to severe plaque psoriasis	Phase III AMAGINE-1 NCT01708590	N = 661	<ul style="list-style-type: none"> Arm 1: 210 mg brodalumab SC Arm 2: 140 mg brodalumab SC Arm 3: placebo SC 	<ul style="list-style-type: none"> PASI at wk 12 Static physician's global assessment (sPGA) at wk 12 	<ul style="list-style-type: none"> Completed OLE ongoing
Moderate to severe plaque psoriasis	Phase III AMAGINE-2 NCT01708603	N = 1,800	<ul style="list-style-type: none"> Arm 1: 210 mg brodalumab SC Arm 2: 140 mg brodalumab SC Arm 3: 45 or 90 mg ustekinumab SC Arm 4: placebo SC 	<ul style="list-style-type: none"> PASI at wk 12 Static physician's global assessment (sPGA) at wk 12 	<ul style="list-style-type: none"> Completed OLE ongoing
Moderate to severe plaque psoriasis	Phase III AMAGINE-3 NCT01708629	N = 1,881	<ul style="list-style-type: none"> Arm 1: 210 mg brodalumab SC Arm 2: 140 mg brodalumab SC Arm 3: 45 or 90 mg ustekinumab SC Arm 4: placebo SC 	<ul style="list-style-type: none"> PASI at wk 12 Static physician's global assessment (sPGA) at wk 12 	<ul style="list-style-type: none"> Completed OLE ongoing
Adult subjects with psoriatic arthritis	Phase III AMVISION-1 NCT02029495	N = 630	<ul style="list-style-type: none"> Arm 1: 210mg brodalumab SC Arm 2: 140 mg brodalumab SC Arm 3: placebo SC 	Primary: <ul style="list-style-type: none"> ACR20 response at wk 16 Secondary: <ul style="list-style-type: none"> Radiographic assessment of joints PASI 75, HAQ-DI and PSI 	<ul style="list-style-type: none"> FPD: Q1 14 Recruitment ongoing Est. primary completion: H1 16
Adult subjects with psoriatic arthritis	Phase III AMVISION-2 NCT02024646	N = 495	<ul style="list-style-type: none"> Arm 1: 210mg brodalumab SC Arm 2: 140 mg brodalumab SC Arm 3: placebo SC 	<ul style="list-style-type: none"> ACR20 response at wk 16 	<ul style="list-style-type: none"> FPD: Q1 14 Recruitment ongoing Est. primary completion: H1 16
Moderate to severe psoriatic arthritis	Phase II NCT01516957	N = 156	<ul style="list-style-type: none"> Arm 1: 280 mg brodalumab SC Arm 2: 210 mg brodalumab SC Arm 3: 140 mg brodalumab SC Arm 4: placebo SC 	<ul style="list-style-type: none"> ACR20 response at wk 12 	<ul style="list-style-type: none"> Completed OLE ongoing



PT003 (LABA/LAMA)

COPD

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Moderate to very severe COPD	Phase III PINNACLE 1 NCT01854645	N = 2,103	Treatment (24-week Treatment Period) <ul style="list-style-type: none"> • Arm 1: GFF MDI (PT003) 14.4/9.6 µg BiD • Arm 2: GP MDI (PT001) 14.4 µg BiD • Arm 3: FF MDI (PT005) 9.6 µg BiD • Arm 4: Open-label tiotropium bromide inhalation powder 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	<ul style="list-style-type: none"> • Change from baseline in morning pre-dose trough FEV₁ 	<ul style="list-style-type: none"> • FPD: Q2 13 • LSI: Q3 14 • Topline results: Q1 15* • Est. external presentation: 2016 * Clinically completed
Moderate to very severe COPD	Phase III PINNACLE 2 NCT01854658	N = 1,618	Treatment (24-week Treatment Period) <ul style="list-style-type: none"> • Arm 1: GFF MDI (PT003) 14.4/9.6 µg BiD • Arm 2: GP MDI (PT001) 14.4 µg BiD • Arm 3: FF MDI (PT005) 9.6 µg BiD • Arm 4: Placebo MDI BiD Multicenter, randomized, double-blind, parallel group, chronic dosing and placebo-controlled Estimated time from FSFV to DBL is approximately 20 months. US	<ul style="list-style-type: none"> • Change from baseline in morning pre-dose trough FEV 	<ul style="list-style-type: none"> • FPD: Q3 13 • LSI: Q3 14 • Topline results: Q2 15* * Clinically completed
Moderate to very severe COPD	Phase III PINNACLE 3 NCT01970878	N = 850	Treatment (28-week Treatment Period) <ul style="list-style-type: none"> • Arm 1: GFF MDI (PT003) 14.4/9.6 µg BiD • Arm 2: GP MDI (PT001) 14.4 µg BiD • Arm 3: FF MDI (PT005) 9.6 µg BiD • Arm 4: Open-label tiotropium bromide inhalation powder QD Multi-center, randomized, double-blind, parallel-group and active-controlled Estimated time from FSFV to DBL is approximately 16 months. US, Australia, New Zealand	<ul style="list-style-type: none"> • Overall safety, tolerability and efficacy 	<ul style="list-style-type: none"> • FPD: Q4 13 • LSI: Q3 14 • Topline results: Q2 15* * Clinically completed



PT003 (LABA/LAMA)

COPD

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Moderate to severe COPD	Phase IIIb (Dose Indicator Study) NCT02268396	N = 150	Treatment (5- to 6- week Treatment Period) <ul style="list-style-type: none"> GFF 14.4/9.6 µg Placebo MDI BID Open-label and multiple-center 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 .	<ul style="list-style-type: none"> FPD: Q4 14 LSI: Q4 14 Topline results: Q1 15* * Clinically completed
Moderate to severe COPD	Phase III (Spacer Study) NCT02454959	N = 60	Treatments (2 week treatment Period) <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Change from morning pre-dose trough FEV₁, 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 C_{max}, AUC₀₋₁₂, AUC_{0-t}, t_{max}. Other PD/PK parameters may be calculated, as appropriate 	<ul style="list-style-type: none"> FPD: Q2 15 LSI: Q2 15 Est. topline results: Q3 15
Moderate to very severe COPD	Phase III (Asia Pacific study) NCT02343458	N = 1,614	Treatments (24-week Treatment Period) <ul style="list-style-type: none"> GFF 14.4/9.6 µg (N=514) GP 14.4 µg (N=440) FF 9.6 µg (N=440) Placebo (N=220) <ul style="list-style-type: none"> 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-Center Estimated time from FSFV to DBL is approximately 20 months. US, UK, Germany, Costa Rica, Hungary, Poland, Russia, South Korea, Taiwan, China, Japan	<ul style="list-style-type: none"> 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] 	<ul style="list-style-type: none"> FPD: Q215 LSI: Q2 16 Est. topline results: H2 16



PT003 (LABA/LAMA)

COPD

Patient population	Study phase	Number of patients	Design (G = Glycopyrronium, F = Formoterol fumarate)	Endpoints	Status
Moderate to severe COPD	Phase IIIb (24 Hr Lung Function Placebo) NCT02347085	N = 40	Treatments (8-week Treatment Period) <ul style="list-style-type: none"> GFF MDI 14.4/9.6 µg BID Placebo MDI BID Randomized, 2-period, 2-treatment Double-blind, Multi-center and Crossover Estimated time from FSFV to DBL is approximately 7 months, US	FEV1 AUC0-24 on Day 29	<ul style="list-style-type: none"> FPD: Q1 15 LSI: Q2 15 Est. topline results: Q3 15
Moderate to severe COPD	Phase IIIb (24 Hr Lung Function Active) NCT02347072	N = 80	Treatments (12-week Treatment Period) <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> FPD: Q1 15 LSI: Q2 15 Est. topline results: Q3 15



PT010 (LABA/LAMA/ICS)

COPD & Asthma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Moderate to severe COPD	Phase II (BFF Dose-ranging) NCT02196077	N = 180	<ul style="list-style-type: none"> • Arm 1: BFF MDI 320/9.6 µg BiD • Arm 2: BFF MDI 160/9.6 µg BiD • Arm 3: BFF MDI 80/9.6 µg BiD • Arm 4: BD MDI 320 µg BiD • Arm 5: FF MDI 9.6 µg BiD Randomized, 4-period, 5-treatment incomplete-block and crossover Estimated time from FSFV to DBL is approximately 7 months. US	<ul style="list-style-type: none"> • Forced expiratory volume in 1 second area under the curve from 0 to 12 hours (FEV₁ AUC₀₋₁₂) 	<ul style="list-style-type: none"> • FPD: Q2 14 • LSI: Q3 14 • Topline results: Q2 15* * Clinically completed
Adult mild to moderate persistent asthma	Phase II (BD Dose-ranging in Asthma) NCT02105012	N = 150	<ul style="list-style-type: none"> • Arm 1: BD MDI 320 µg BiD • Arm 2: BD MDI 160 µg BiD • Arm 3: BD MDI 80 µg BiD • Arm 4: BD MDI 40 µg BiD • Arm 5: Placebo MDI BiD Randomized, 4-period, 5-treatment incomplete-block and crossover 4 week Estimated time from FSFV to DBL is approximately 18 months. US	<ul style="list-style-type: none"> • Change from baseline in morning pre-dose trough forced expiratory volume in one second (FEV₁) 	<ul style="list-style-type: none"> • FPD: Q2 14 • LSI: Q4 14* * Clinically completed
Healthy volunteers	Phase I (BGF PK study) NCT02189304	N = 72	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Overall safety • PK parameters AUC₀₋₁₂ and C_{max} 	<ul style="list-style-type: none"> • FPD: Q3 14 • LSI: Q3 14 • Topline results: Q4 14* * Clinically completed



PT010 (LABA/LAMA/ICS)

COPD & Asthma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Moderate to very severe COPD	Phase III (Exacerbation study) ETHOS NCT02465567	N = 10,000	Treatments (1-year Treatment Period) <ul style="list-style-type: none"> • BGF MDI 320/14.4/9.6 µg • BGF MDI 160/14.4/9.6 µg • BFF MDI 320/9.6 µg • GFF MDI 14.4/9.6 µg Randomized, double-blind, multi-center and parallel-group Estimated time from FSFV to DBL is approximately 3 years. Multi-country	<ul style="list-style-type: none"> • Rate of moderate or severe COPD exacerbations • Time to first moderate or severe COPD exacerbation 	<ul style="list-style-type: none"> • FPD: Q3 15 • LSI: 2017 • Est. topline results: 2018
Moderate to very severe COPD	Phase III (Lung function study) NCT (TBD)	N = 1,800	Treatments (24-week Treatment Period) <ul style="list-style-type: none"> • 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-center Estimated time from FSFV to DBL is approximately 2 years. Multi-country	Co-Primary Endpoints (EU): <ul style="list-style-type: none"> • 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): <ul style="list-style-type: none"> • 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): <ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • FPD: Q3 15 • LSI: 2017 • Est. topline results: 2017



PT010 (LABA/LAMA/ICS)

COPD & Asthma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Moderate to very severe COPD	Phase III (Long-term safety extension for Japan) NCT (TBD)	N = 320	Treatments (28-Week Treatment Period) <ul style="list-style-type: none"> • 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, chronic dosing, and multi-center Estimated time from FSFV to DBL is approximately 26 months. Japan	<ul style="list-style-type: none"> • Change from baseline in morning pre-dose trough FEV1 over 52 weeks of treatment 	<ul style="list-style-type: none"> • FPD: Q3 16 • LSI: TBD • Est. topline results: 2017
Moderate to very severe COPD	Phase III (Long-term BMD and Ocular Safety) NCT (TBD)	N = 500	Treatments (52-week Treatment Period) <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Change from baseline in BMD of the lumbar spine measured using DXA scans of L1-L4 at Week 52 Ocular Sub-study Safety Endpoint: <ul style="list-style-type: none"> • Change from baseline in LOCS III at Week 52 	<ul style="list-style-type: none"> • FSD: Q3 15 • LSI: TBD • Est. topline results: TBD
Japanese healthy volunteers	Phase I (BGF PK in Japanese Subjects) NCT02197975	N = 20	Treatment (2-week Treatment Period) <ul style="list-style-type: none"> • Arm 1: BGF MDI 320/14.4/9.6 µg • Arm 2: BGF MDI 160/14.4/9.6 µg • Arm 3: Placebo MDI Randomized, double-blind, placebo-controlled, 2-period, ascending-dose and crossover Estimated time from FSFV to DBL is approximately 8 weeks. Japan	<ul style="list-style-type: none"> • Overall safety • PK parameters AUC₀₋₁₂ and C_{max} 	<ul style="list-style-type: none"> • FPD: Q3 14 • LSI: Q3 14 • Topline results: Q4 14* * Clinically completed
Japanese healthy volunteers	Phase I (GFF PK in Japanese Subjects) NCT02196714	N = 24	Treatment (4-day Treatment Period) <ul style="list-style-type: none"> • Arm 1: GFF MDI 14.4/9.6 µg • Arm 2: GFF MDI 28.8/9.6 µg • Arm 2: GP MDI 14.4 µg • Arm 2: GP MDI 28.8 µg Randomized, double-blind, single-dose, 4-Period, 4-treatment and crossover Estimated time from FSFV to DBL is approximately 13 weeks. Japan	<ul style="list-style-type: none"> • Overall safety • PK parameters AUC₀₋₁₂ and C_{max} 	<ul style="list-style-type: none"> • FPD: Q3 14 • LSI: Q3 14 • Topline results: Q4 14* * Clinically completed



Benralizumab (IL-5R α mAb)

Asthma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA \pm chronic OCS Age 12 – 75yrs	Phase III CALIMA NCT01914757	N = 1026 HD + ~200 MD	<ul style="list-style-type: none"> • Arm 1: 30 mg Q8w SC • Arm 2: 30 mg Q4w SC • Arm 3: Placebo SC 56-week study Global study – 11 countries	<ul style="list-style-type: none"> • Annual asthma exacerbation rate • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalization visits, PK, and IM 	<ul style="list-style-type: none"> • FPD: Q4 13 • Est. completion: H1 16
Severe asthma, inadequately controlled despite background controller medication HD ICS + LABA \pm chronic OCS Age 12 – 75 yrs	Phase III SIROCCO NCT01928771	N = 1,134	<ul style="list-style-type: none"> • Arm 1: 30 mg Q8w SC • Arm 2: 30 mg Q4w SC • Arm 3: Placebo SC 48-week study Global study – 17 countries	<ul style="list-style-type: none"> • Annual asthma exacerbation rate • Assess pulmonary function, asthma symptoms, other asthma control metrics, ER/ED hospitalization visits, PK, and IM 	<ul style="list-style-type: none"> • FPD: Q4 13 • Est. completion: H1 16
Severe asthma, inadequately controlled on high dose inhaled corticosteroid plus long-acting β 2 agonist and chronic oral corticosteroid therapy Age 18 – 75 yrs	Phase III ZONDA NCT02075255	N = 210	<ul style="list-style-type: none"> • Arm 1: 30 mg Q8w SC • Arm 2: 30 mg Q4w SC • Arm 3: Placebo SC 46-week study Global study – 7 countries	<ul style="list-style-type: none"> • Reduction of oral corticosteroid dose 	<ul style="list-style-type: none"> • FPD: Q3 14 • Est. completion: H1 16



Benralizumab (IL-5R α mAb)

Asthma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Asthmatic with FEV1 (50-90% predicted) on low to medium dose inhaled corticosteroid Age 18 – 75 yrs	Phase III BISE NCT02322775	N = 200	<ul style="list-style-type: none"> • Arm 1: 30 mg Q4w SC • Arm 3: Placebo SC 12-week study Global study	<ul style="list-style-type: none"> • Pulmonary function (FEV1) 	<ul style="list-style-type: none"> • FPD: Q1 15 • Est. completion: H1 16
Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA \pm chronic OCS Age 12 – 75yrs	Phase III BORA NCT02258542	N = 2,550	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Safety and tolerability 	<ul style="list-style-type: none"> • FPD: Q4 14 • Est. completion: 2017
Severe asthma, inadequately controlled despite background controller medication, MD & HD ICS + LABA \pm chronic OCS Age 18 – 75yrs	Phase III GREGALE NCT02417961	N = 120	<ul style="list-style-type: none"> • Arm 1: 30 mg Q4w SC 28-week (adults) Global study	<ul style="list-style-type: none"> • Functionality, Reliability, and Performance of a Pre-filled Syringe With Benralizumab Administered at Home 	<ul style="list-style-type: none"> • FPD: Q2 15 • Est. completion: H2 16



Benralizumab (IL-5R α mAb)

COPD

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Moderate to very severe Chronic Obstructive Pulmonary Disease (COPD) with exacerbation history	Phase III TERRANOVA NCT02155660	N = 2,088	<ul style="list-style-type: none"> • Arm 1: 10 mg Q8w SC • Arm 2: 30 mg Q4w SC • Arm 3: 100 mg Q8w SC • Arm 4: Placebo SC 48-week study Global study – 15 countries	<ul style="list-style-type: none"> • Rate of COPD exacerbation 	<ul style="list-style-type: none"> • FPD: Q3 14 • Est. completion: 2017
Moderate to very severe Chronic Obstructive Pulmonary Disease (COPD) with exacerbation history	Phase III GALATHEA NCT02138916	N = 1,566	<ul style="list-style-type: none"> • Arm 1: 30 mg Q4w SC • Arm 2: 100 mg Q8w SC • Arm 3: Placebo SC 48-week study Global study – 21 countries	<ul style="list-style-type: none"> • Rate of COPD exacerbation 	<ul style="list-style-type: none"> • FPD: Q3 14 • Est. completion: 2017



Tralokinumab (IL-13 mAb)

Asthma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Adults with uncontrolled severe asthma	Phase III STRATOS 1 NCT02161757	N = 1,140	<p><u>Cohort 1:</u></p> <ul style="list-style-type: none"> • Arm 1: Tralokinumab dose regimen 1, SC • Arm 2: Placebo SC <p><u>Cohort 2:</u></p> <ul style="list-style-type: none"> • Arm 1: Tralokinumab dose regimen 2, SC • Arm 2: Placebo SC <p>2:1 randomisation in both cohorts</p> <p>Global study – 16 countries</p>	<p>Primary:</p> <ul style="list-style-type: none"> • Asthma exacerbation rate reduction <p>Key Secondary:</p> <ul style="list-style-type: none"> • Effect of tralokinumab on measures of pulmonary function (FEV1), asthma symptoms (Asthma Daily Diary), asthma control (ACQ-6) and asthma related QoL (AQLQ (S) +12) 	<ul style="list-style-type: none"> • FPD: Q3 14 • LPD: H1 16 • Est. topline results: 2017
Adults with uncontrolled severe asthma	Phase III STRATOS 2 NCT02194699	N = 770	<ul style="list-style-type: none"> • Arm 1: Tralokinumab SC • Arm 2: Placebo SC <p>1:1 randomisation</p> <p>Global study – 13 countries including Japan</p>	<p>Primary:</p> <ul style="list-style-type: none"> • Asthma exacerbation rate reduction <p>Key Secondary:</p> <ul style="list-style-type: none"> • Effect of tralokinumab on measures of pulmonary function (FEV1), asthma symptoms (Asthma Daily Diary), asthma control (ACQ-6) and asthma related QoL (AQLQ (S) +12) 	<ul style="list-style-type: none"> • FPD: Q1 15 • LPD: H2 16 • Est. topline results: 2017
Adults with oral corticosteroid dependent asthma	Phase III TROPOS NCT02281357	N = 120	<ul style="list-style-type: none"> • Arm 1: Tralokinumab SC • Arm 2: Placebo SC <p>1:1 randomisation</p> <p>Global studies - 5 countries</p>	<p>Primary:</p> <ul style="list-style-type: none"> • % Change in OCS dose <p>Key Secondary:</p> <ul style="list-style-type: none"> • Proportion of subjects achieving final daily OCS dose ≤5 mg • Proportion of subjects achieving ≥50% reduction in OCS dose 	<ul style="list-style-type: none"> • FPD: Q1 15 • LPD: H2 16 • Est. topline results: 2017



Anifrolumab (type I IFN receptor mAb)

Systemic Lupus Erythrmatosus (SLE)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Moderate to severe Systemic Lupus Erythematosis (SLE) Tulip SLE 1	Phase III NCT02446912	N = 450	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> FPD: Q3 15 Est. topline results: 2018
Moderate to severe Systemic Lupus Erythematosis (SLE) Tulip SLE 2	Phase III NCT02446899	N = 360	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> FPD: Q3 15 Est. topline results: 2018
Moderate to severe SLE patients	Phase II NCT01438489	N = 307 (final)	<ul style="list-style-type: none"> Arm 1: 300 mg IV MEDI-546 Q4W for 48 weeks Arm 2: 1000 mg IV MEDI-546 Q4W for 48 weeks Arm 3: placebo IV Q4W for 48 weeks 	Response in SLE responder index at 6 months	<ul style="list-style-type: none"> FPD: Q1 12 Topline results: Q3 14
Moderate to severe SLE patients	Phase II NCT01753193	N = 240	<ul style="list-style-type: none"> Arm 1: MEDI-546, IV Q4W for 104 weeks 	Open-label extension to evaluate long-term safety and tolerability	<ul style="list-style-type: none"> FPD: Q1 13 Est. topline results: 2017
Japanese SLE patients	Phase II NCT01559090	N = 17	<p>Open-label, dose escalation study:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Topline results: Q1 15



Roxadustat (HIF-PHI)

Chronic Kidney Disease (CKD)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Anaemia in Chronic Kidney Disease patients not receiving dialysis	Phase III ANDES NCT02446912	N = 450	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> FPD: Q3 15 Est. topline results: 2018
Anaemia in Chronic Kidney Disease patients not receiving dialysis	Phase III ANDES NCT01750190	N = 600	<ul style="list-style-type: none"> Arm 1: Roxadustat Arm 2: Placebo Global study – 16 countries	Haemoglobin response	<ul style="list-style-type: none"> FPD: Q4 12 Est. completion: 2017 Sponsored by FibroGen
	Phase III ALPS NCT01887600	N = 600	<ul style="list-style-type: none"> Arm 1: Roxadustat Arm 2: Placebo Global study – 14 countries	Haemoglobin response	<ul style="list-style-type: none"> FPD: Q2 13 Est. completion: H1 16 Sponsored by Astellas
	Phase III DOLOMITES NCT02021318	N = 570	<ul style="list-style-type: none"> Arm 1: Roxadustat Arm 2: Darbepoetin alfa Global study – 17 countries	Haemoglobin response	<ul style="list-style-type: none"> FPD: Q1 14 Est. completion: 2017 Sponsored by Astellas
	Phase III OLYMPUS NCT02174627	N = 2,600	<ul style="list-style-type: none"> Arm 1: Roxadustat Arm 2: Placebo Global study – 26 countries	MACE	<ul style="list-style-type: none"> FPD: Q3 14 Est completion: 2017 Sponsored by AstraZeneca
Anaemia in CKD in patients receiving dialysis	Phase III ROCKIES NCT02174731	N = 1,425	<ul style="list-style-type: none"> Arm 1: Roxadustat Arm 2: Epoetin alfa Global study – 20 countries	MACE	<ul style="list-style-type: none"> FPD: Q3 14 Est completion: 2017 Sponsored by AstraZeneca
	Phase III SIERRAS NCT02273726	N = 600	<ul style="list-style-type: none"> Arm 1: Roxadustat Arm 2: Epoetin alfa Global study – 1-4 countries	Haemoglobin response	<ul style="list-style-type: none"> FPD: Q4 14 Est. completion: 2017 Sponsored by FibroGen
	Phase III PYRENEES NCT02278341	N = 750	<ul style="list-style-type: none"> Arm 1: Roxadustat Arm 2: Erythropoiesis Stimulating Agent Global study – 14 countries	Haemoglobin response	<ul style="list-style-type: none"> FPD: Q4 14 Est. completion: 2017 Sponsored by Astellas
Anaemia in newly initiated dialysis patients	Phase III HIMALAYAS NCT02052310	N = 750	<ul style="list-style-type: none"> Arm 1: Roxadustat Arm 2: Epoetin alfa Global study – 21 countries	Haemoglobin response	<ul style="list-style-type: none"> FPD: Q4 13 Est. completion: 2017 Sponsored by FibroGen



AZD9291 (Highly selective, irreversible EGFR TKI)

Non-small cell lung cancer (NSCLC)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	Phase III AURA3 NCT02151981	N = 410	<ul style="list-style-type: none"> Arm 1: AZD9291 80mg QD Arm 2: pemetrexed 500mg/m² + carboplatin AUC5 or pemetrexed 500mg/m² + cisplatin 75mg/m² (2:1 randomization) Global study	<ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint PFS OS and QoL as secondary endpoints 	<ul style="list-style-type: none"> FPD: Q3 14 Est. primary completion: H2 16
Advanced EGFRm NSCLC 1L	Phase III FLAURA NCT02296125	N = 650	<ul style="list-style-type: none"> Arm 1: AZD9291 80mg Arm 2: erlotinib 150mg or gefitinib 250 mg (dealers choice); 1:1 randomisation Global study	<ul style="list-style-type: none"> PFS OS and QoL as secondary endpoints 	<ul style="list-style-type: none"> FPD: Q1 15 Est. completion: 2017
Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	Phase II AURA2 NCT02094261	N = 175	<ul style="list-style-type: none"> AZD9291 80 mg QD Global study	<ul style="list-style-type: none"> ORR PFS and OS secondary endpoints 	<ul style="list-style-type: none"> FPD: Q2 14 Enrolment complete (N=210)
Advanced EGFRm NSCLC TKI failure +/- primary resistance mutation T790M	Phase I/II AURA NCT01802632	N ~ 500	<ul style="list-style-type: none"> Dose escalation study Ph II Extension cohort (T790M only) 80mg QD Global study	<ul style="list-style-type: none"> Safety and tolerability ORR PFS and OS secondary endpoints 	<ul style="list-style-type: none"> FPD: Q1 13 Enrolment complete (N=201 in extension portion)
Advanced EGFRm NSCLC TKI failure	Phase Ib TATTON NCT02143466	N ~ 90	<ul style="list-style-type: none"> Arm 1: AZD9291 + MEDI4736 Arm 2: AZD9291 + AZD6094 Arm 3: AZD9291 + selumetinib Global study	<ul style="list-style-type: none"> Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity 	<ul style="list-style-type: none"> FPD: Q3 14 Est. completion: Q3 15
Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	Phase III CAURAL NCT02454933	N = 350	<ul style="list-style-type: none"> Arm 1: AZD9291 (80mg QD) + MEDI4736 1(0mg/kg q2w (IV infusion)) Arm 2: AZD9291 (80mg QD) Global study	<ul style="list-style-type: none"> PFS ORR, OS, QoL as secondary endpoints 	<ul style="list-style-type: none"> FPD: Q3 15 Est. completion: 2018
Advanced EGFRm NSCLC TKI failure and primary resistance mutation T790M	Phase II NCT02442349	N = 175	<ul style="list-style-type: none"> AZD9291 80 mg QD Asia Pacific Regional Study	<ul style="list-style-type: none"> ORR PFS and OS secondary endpoints 	<ul style="list-style-type: none"> FPD: Q3 15 Est. primary completion: H1 16



Selumetinib (AZD6244) (MEK-inhibitor)

Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
2L KRAS ^m positive NSCLC	Phase III SELECT-1 NCT01933932	N = 634	<ul style="list-style-type: none"> Arm 1: Selumetinib 75mg BiD + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle Arm 2: Placebo BiD + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle <p>Global study – 26 countries</p>	<ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint 	<ul style="list-style-type: none"> FPD: Q4 13 LPD: H1 16 Est. topline results: H2 16
Differentiated thyroid cancer	Phase III ASTRA NCT01843062	N = 304	<ul style="list-style-type: none"> Arm 1: Selumetinib 75mg BiD 5 weeks duration + RAI 100mCi^a Arm 2: Placebo BiD 5 weeks duration + RAI 100mCi^a <p>Global study – 8 countries</p> <p>^a Single dose of 100mCi ¹³¹I administered following 4 weeks of selumetinib (or placebo).</p>	<ul style="list-style-type: none"> Complete remission (CR) rate at 18 months post-RAI Clinical remission rate at 18 m post RAI (per SoC) 	<ul style="list-style-type: none"> FPD: Q3 13 LPD: H1 16 Est. topline results: 2017
Pediatric NF1 ¹	Phase II NCT01362803 (current Ph I) – partnered (NCI)	N = minimum of 50 symptomatic pts	<ul style="list-style-type: none"> Single Arm: Selumetinib 25mg/m² BID with 2 strata: <ul style="list-style-type: none"> Stratum 1: PN related morbidity present at enrolment Stratum 2: No PN related morbidity present at enrolment 	<ul style="list-style-type: none"> Complete partial and complete response rate measured by volumetric MRI; Duration of response and functional outcomes/QoL 	<ul style="list-style-type: none"> FPD: Q3 15 LPD: H2 16 Est. topline results: 2017
2L KRAS ^m negative NSCLC	Phase II SELECT-2 NCT01750281	N = 265	<ul style="list-style-type: none"> Arm 1: Selumetinib 75mg BiD + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle Arm 2: Selumetinib 75mg BiD + docetaxel 60 mg/m² IV on day 1 of each 21 day cycle Arm 3: Placebo BiD + docetaxel 75 mg/m² IV on day 1 of each 21 day cycle <p>Global study – 7 countries</p>	<ul style="list-style-type: none"> Progression Free Survival Overall Survival is a secondary endpoint. 	<ul style="list-style-type: none"> FPD: Q1 13 LPD: Q3 15 Est. topline results: H1 16

¹ Clintrials.gov to be updated with Phase II study, currently showing reference to Phase I



Durvalumab (MEDI4736) (PD-L1 mAb)

Non-small cell lung cancer (NSCLC)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Unresectable Stage III NSCLC patients following platinum-based concurrent chemo-radiation therapy	Phase III PACIFIC NCT02125461	N = 702	<ul style="list-style-type: none"> Arm 1: MEDI4736 IV Q2W Arm 2: placebo Global study	<ul style="list-style-type: none"> Progression Free Survival (PFS) Overall Survival (OS) 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: H2 16 Est. completion: 2017
Stage IIIB-IV NSCLC patients PD-L1+ve patients	Phase II ATLANTIC NCT02087423	N = 188	<ul style="list-style-type: none"> Arm 1: MEDI4736 IV Q2W (EFGR/ALK WT) Arm 2: MEDI4736 IV Q2W (EFGR/ALK M+) Global study – 18 countries	<ul style="list-style-type: none"> Objective Response Rate Secondary endpoints include duration of response, progression free survival and overall survival 	<ul style="list-style-type: none"> FPD: Q1 14 LPD: Q2 15 First data: H2 15 Est. completion: 2017



Durvalumab (MEDI4736) (PD-L1 mAb)

Non-small cell lung cancer (NSCLC)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Adjuvant NSCLC patients IB (≥4cm) – IIIA resected NSCLC (incl. EGFR/ALK pos)	Phase III ADJUVANT NCT02273375 Partnered with NCIC CTG	N = 1,100	<ul style="list-style-type: none"> Arm 1: MEDI4736 10mg/kg IV Q2W x 6 mos followed by MEDI4736 20 mg/kg IV Q4W x 6 mos Arm 2: Placebo Global Study	<ul style="list-style-type: none"> mRFS OS 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: 2018 Est. completion: 2020
Stage IV squamous NSCLC patients Biomarker-targeted 2L therapy	Phase II/III Lung Master Protocol NCT02154490 Partnered with NCI, FNIH, and SWOG	N = 400 (4736 substudy only); revised to 100 (pending CTEP approval)	Umbrella study with 5 arms based on biomarker expression <ul style="list-style-type: none"> Arm 1: MEDI4736 (non-match for other biomarker driven substudies) IVQ2W vs. Docetaxel; revised to single arm MEDI4736 PhII only (pending CTEP approval) Arm 2: PI3K Inhibitor vs. docetaxel Arm 3: CDK4/6 inhibitor vs. docetaxel Arm 4: AZD4547 (FGFR inhibitor) vs. docetaxel Arm 5: C-MET/HGFR inhibitor + erlotinib vs. Erlotinib (Substudy is closed) 	Overall Master Protocol (co-primary) <ul style="list-style-type: none"> Progression Free Survival (PFS) Overall Survival (OS) Arm 1 (co-primary) <ul style="list-style-type: none"> ORR, all patients ORR, PDL1 + 	<ul style="list-style-type: none"> FPD: Q3 14 LPD: Q3 15 (Phase II) Est. completion: H1 16 (Phase II)
Stage IIIB-IV NSCLC patients	Phase I/II Sequencing Study NCT02179671	N = 72	<ul style="list-style-type: none"> Arm 1: Iressa initially then switch to MEDI4736 IVQ2W Arm 2: AZD9291 then switch to MEDI4736 Arm 3: Selumetinib + Docetaxel then switch to MEDI4736 Arm 4: tremelimumab then switch to MEDI4736 	<ul style="list-style-type: none"> Complete Response Rate ORR, Disease Control Rate 	<ul style="list-style-type: none"> FPD: Q3 14 LPD: Q2 15 Est. completion: H2 16



Durvalumab (MEDI4736) (PD-L1 mAb)

SCCHN and other solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
SCCHN 2L therapy	Phase II HAWK NCT02207530	N = 112	<ul style="list-style-type: none"> Single-arm: MEDI4736 IVQ2W 	<ul style="list-style-type: none"> ORR 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: Q3 15 First data: H2 16
Solid tumours	Phase I NCT02301130 Partnered with KHK	N = 108	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Safety and Tolerability MTD ORR, DoR, DCR, PFS, OS 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: Q4 15 Est. completion: H2 16
Solid tumours (all-comers)	Phase I NCT01938612	N = 118	<ul style="list-style-type: none"> Dose Escalation: 3 cohorts at Q2W and 1 cohort at Q3W Dose Expansion: Multiple solid tumour types <p>Study conducted in Japan</p>	<ul style="list-style-type: none"> Safety Optimal biologic dose 	<ul style="list-style-type: none"> FPD: Q3 13 LPD: Q4 14 Est. completion: H1 16



Tremelimumab (CTLA-4 mAb)

Mesothelioma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Patients with unresectable pleural or peritoneal malignant mesothelioma	Phase II DETERMINE NCT01843374	N = 564	<ul style="list-style-type: none">• Arm 1: Tremelimumab IV• Arm 2: Placebo	<ul style="list-style-type: none">• Overall survival (OS)	<ul style="list-style-type: none">• FPD: Q2 13• LPD: Q4 14• First data: H2 15• Est. completion date: H1 16



Durvalumab (MEDI4736) (PD-L1 mAb) + Tremelimumab (CTLA-4 mAb) Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Stage IIIB-IV 3L NSCLC patients who have not be tested positive for EGFR/AIk mutation	Phase III ARCTIC NCT02352948	N = 900	<p>Substudy A</p> <ul style="list-style-type: none"> Arm 1: MEDI4736 IV Q2W (PD-L1+ patients) vs Arm 2: Standard of Care <p>Substudy B</p> <ul style="list-style-type: none"> Arm 3: MEDI4736+tremelimumab (PD-L1 –ve patients) vs Arm 4: Standard of Care Arm 5: tremelimumab (PD-L1 –ve patients) Arm 6: MEDI4736 (PD-L1 –ve patients) Dose and Schedule for Combination Arm under discussion 	<ul style="list-style-type: none"> Progression Free Survival (PFS) Overall Survival (OS) 	<p>Monotherapy arm</p> <ul style="list-style-type: none"> FPD: Q2 15 LPD: H1 16 Est. completion: 2017 (PFS) <p>Combination therapy</p> <ul style="list-style-type: none"> FPD: Q2 15 LPD: H2 16 Est. completion: 2017 (PFS)
NSCLC 1L	Phase III MYSTIC NCT02453282	N = 675	<ul style="list-style-type: none"> Arm 1: MEDI4736 Arm 2: MEDI4736 + tremelimumab Arm 3: Standard of care 	<ul style="list-style-type: none"> Progression Free Survival 	<ul style="list-style-type: none"> FPD: Q3 15 LSD: H2 16 Est. completion: 2017
SCCHN 2L	Phase II CONDOR NCT02319044	N = 240	<ul style="list-style-type: none"> Arm 1: MEDI4736 Arm 2: Tremelimumab Arm 3: Tremelimumab + MEDI4736 	<ul style="list-style-type: none"> ORR 	<ul style="list-style-type: none"> FPD: Q2 15 LPD: H1 16 First data: H2 16
Solid tumors (treme Phase I)	Phase I combination in advanced solid tumours in Japanese patients NCT02141347	N = 22	<ul style="list-style-type: none"> Tremelimumab + MEDI4736 Dose Escalation study Tremelimumab Q4W/Q12W 3-10mg/kg Tremelimumab Q4W/Q12W X mg/kg + MEDI4736 Q4W X mg/kg 	<ul style="list-style-type: none"> Safety Optimal biologic dose 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: Q2 15 Est. completion: Q3 15



Durvalumab (MEDI4736) (PD-L1 mAb) + Tremelimumab (CTLA-4 mAb) Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Patients with with metastatic or recurrent gastric or gastroesophageal junction adenocarcinoma	Phase II NCT02340975	N = 174	<ul style="list-style-type: none">• Arm 1: MEDI4736 + tremelimumab• Arm 2: MEDI4736• Arm 3: tremelimumab• Arm 4: MEDI4736 + tremelimumab	<ul style="list-style-type: none">• Objective response rate• Progression free survival	<ul style="list-style-type: none">• FPD: Q2 15• LSD: H2 16• Est. completion: 2017



Cediranib (VEGF)

Ovarian cancer

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Patients with platinum-sensitive relapsed ovarian cancer	Phase III NCT00532194	N = 486	<ul style="list-style-type: none">• Arm 1: Placebo• Arm 2: concurrent cediranib• Arm 3: concurrent and maintenance cediranib	<ul style="list-style-type: none">• Progression Free Survival	<ul style="list-style-type: none">• FPD: Q2 07• Completed



CAZ-AVI (BLI/cephalosporin SBI)

Infections

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Hospitalised patients with complicated intra-abdominal infections	Phase III RECLAIM-1 NCT01499290	N = 493	<ul style="list-style-type: none"> • Arm 1: CAZ-AVI 2000/500mg plus Metronidazole IV • Arm 2: Meropenem IV Global study – 20 countries	<ul style="list-style-type: none"> • Co primary of: (i) clinical response at TOC (MITT) (ii) clinical response at TOC (i.e. clinically evaluable) 	<ul style="list-style-type: none"> • FPD: Q1 12 • LPD: Q2 14 • Topline results: Q3 14
Hospitalised patients with complicated intra-abdominal infections	Phase III RECLAIM-2 NCT01500239	N = 577	<ul style="list-style-type: none"> • Arm 1: CAZ-AVI 2000/500mg plus Metronidazole IV • Arm 2: Meropenem IV Global study – 21 countries	<ul style="list-style-type: none"> • Co primary of: (i) clinical response at TOC (MITT) (ii) clinical response at TOC (i.e. clinically evaluable) 	<ul style="list-style-type: none"> • FPD: Q2 12 • LPD: Q2 14 • Topline results: Q3 14
Hospitalised adults with complicated urinary tract Infections	Phase III RECAPTURE-1 NCT01595438	N = 563	<ul style="list-style-type: none"> • Arm 1: CAZ-AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • Arm 2: Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim Global study – 26 countries	<ul style="list-style-type: none"> • Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT) 	<ul style="list-style-type: none"> • FPD: Q4 12 • LPD: Q3 14 • Est. topline results: Q3 15
Hospitalised patients with complicated urinary tract infections	Phase III RECAPTURE-2 NCT01599806	N = 583	<ul style="list-style-type: none"> • Arm 1: CAZ-AVI 2000/500mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim • Arm 2: Doripenem 500 mg IV plus either 500 mg of oral ciprofloxacin or 800 mg/160 mg of oral sulfamethoxazole/trimethoprim Global study – 25 countries	<ul style="list-style-type: none"> • Per patient microbiological response at TOC in patients with a cUTI and a Gram-negative pathogen (i.e. mMITT) 	<ul style="list-style-type: none"> • FPD: Q4 12 • LPD: Q3 14 • Est. topline results: Q3 15



CAZ-AVI (BLI/cephalosporin SBI)

Infections

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Patients with complicated urinary tract infections and complicated intra-abdominal infections	Phase III REPRISE NCT01644643	N = 345	<ul style="list-style-type: none"> Arm 1: CAZ-AVI 2000/500mg plus Metronidazole IV Arm 2: Best available therapy Global study – 30 countries	<ul style="list-style-type: none"> Patients with clinical cure at the Test of Cure visit in the microbiological intent to treat analysis set 	<ul style="list-style-type: none"> FPD: Q1 13 LPD: Q3 14 Topline results: Q2 15
Hospitalised patients with complicated intra-abdominal infections	Phase III RECLAIM-3 NCT01726023	N = 441	<ul style="list-style-type: none"> Arm 1: CAZ-AVI 2000/500mg plus Metronidazole IV Arm 2: Meropenem IV Asia-focused study – 3 countries (China, Vietnam & Korea)	<ul style="list-style-type: none"> Clinical Cure at the TOC visit in the MITT analysis set 	<ul style="list-style-type: none"> FPD: Q1 13 LPD: Q1 15 Est. topline results: Q3 15
Hospitalised patients with nosocomial pneumonia infections, including hospital acquired pneumonia (HAP) and ventilator associated pneumonia (VAP)	Phase III REPROVE NCT01808092	N = 1,000	<ul style="list-style-type: none"> Arm 1: CAZ-AVI 2000/500mg IV Arm 2: Meropenem IV Global study – 24 countries	<ul style="list-style-type: none"> Proportion of patients with clinical cure at the TOC visit in the cMITT and CE analysis sets (co-primary analyses) 	<ul style="list-style-type: none"> FPD: Q2 13 LPD: Q4 15 Est. topline results: H1 16



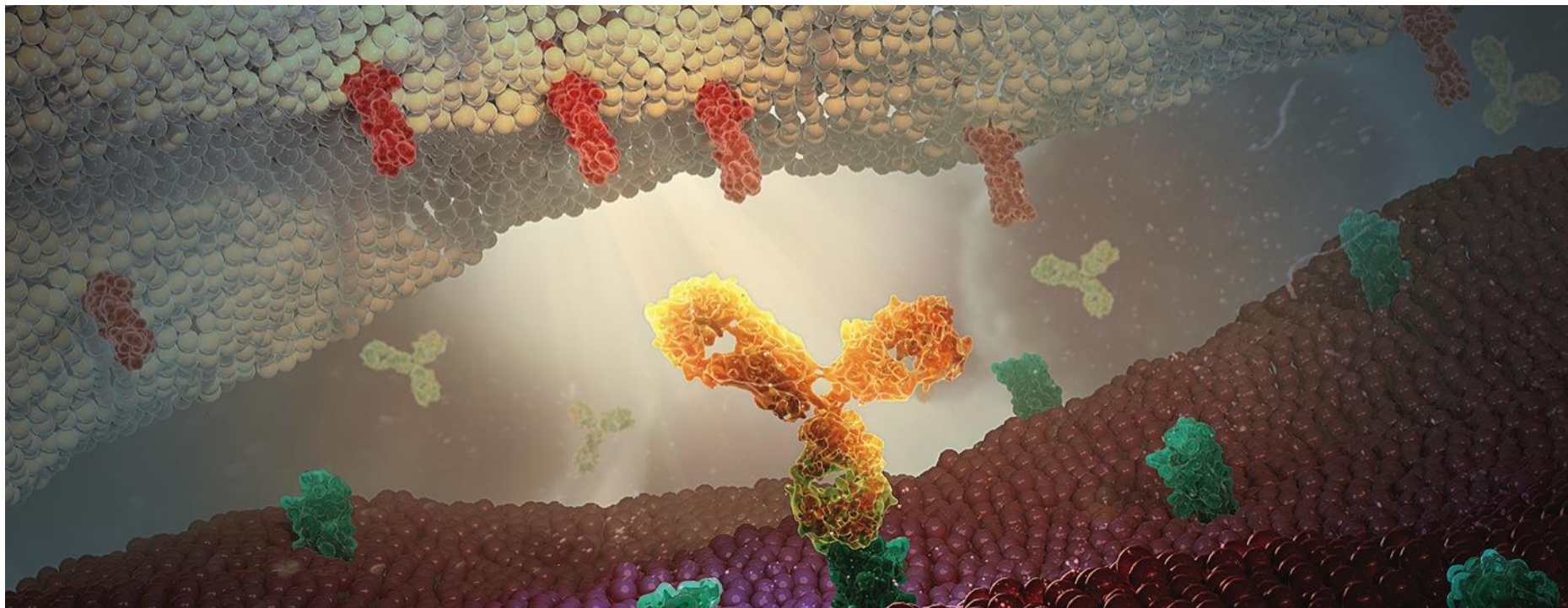
AZD3293 (BACE inhibitor)

Alzheimer's disease

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Alzheimer's disease patients	Phase II/III AMARANTH NCT02245737	N = 2,202	<ul style="list-style-type: none"> • Arm 1: AZD3293 20 mg once daily • Arm 2: AZD3293 50 mg once daily • Arm 3: placebo once daily 24-month treatment duration Global study – approx. 15 countries	<ul style="list-style-type: none"> • Change in Clinical Dementia Rating Sum of Boxes (CDR-SB) • Changes in Cognitive (ADAS-Cog 13) and functional (ADCS-ADL) scales • Changes in biomarkers and imaging assays • Safety and tolerability 	<ul style="list-style-type: none"> • FPD: Q4 14 • LPD: 2017 • Est. topline results: 2019



Early development



AZD2115 (MABA)

COPD

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



AZD7624 (p38 inhibitor)

COPD

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Healthy subjects	Phase I NCT01754844	N = 48	SAD <ul style="list-style-type: none"> Five different dose levels investigated vs placebo Inhaled (nebulised) administration Study conducted in the UK	<ul style="list-style-type: none"> Safety and tolerability following inhaled administration with single ascending dose 	<ul style="list-style-type: none"> FPD: Q1 13 Completed
Healthy subjects and COPD	Phase I NCT01817855	N = 47	MAD <ul style="list-style-type: none"> Different dose levels investigated vs placebo in healthy volunteers and patients with COPD Inhaled (nebulised) administration Study conducted in the UK	<ul style="list-style-type: none"> Safety and tolerability in healthy subjects and patients with COPD following administration of multiple ascending inhaled doses 	<ul style="list-style-type: none"> FPD: Q3 13 Completed
Healthy subjects	Phase Ib LPS NCT01937338	N = 30	<ul style="list-style-type: none"> 2-way cross-over RCT Single administration of 1200µg of AZD7624 or placebo at 0.5 hours prior to lipopolysaccharide (LPS) challenge. Inhaled (nebulised) administration Study conducted in the UK	<ul style="list-style-type: none"> Effect on neutrophils in induced sputum after oral inhalation of LPS, compared to placebo 	<ul style="list-style-type: none"> FPD: Q4 13 Completed
COPD	Phase IIa NCT02238483	N = 212	<ul style="list-style-type: none"> Arm 1: AZD7624, 1.0mg Arm 2: placebo Inhaled (nebulised) administration Study conducted in US, EU, South Africa & South America	<ul style="list-style-type: none"> Effect on rate of exacerbations and lung function compared to placebo 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: Q4 15 Est. topline results: H1 16



AZD7986 (DPP1 inhibitor)

COPD

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Healthy subjects and COPD	Phase I NCT02303574	N = up to 152	Part 1 (SAD) <ul style="list-style-type: none">Five different dose levels investigated vs placebooral administration	<ul style="list-style-type: none">Safety and tolerability and PK following oral administration with single ascending dosePreliminary assessment of the effect of food on the single dose PK parameters of AZD7986	<ul style="list-style-type: none">FPD: Q4 14LPD: Q1 15
			Part 2 (MAD) <ul style="list-style-type: none">Three different dose levels investigated vs placebo in healthy volunteers and patients with COPDoral administration <p>Study conducted in the UK</p>	<ul style="list-style-type: none">Safety and tolerability & PK in healthy subjects following administration of multiple ascending oral dosesNE activity	<ul style="list-style-type: none">FPD: Q1 15LPD: Q3 15Est. completion: Q3 15



AZD7594 (inhaled SGRM)

Asthma/COPD

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Patients with mild to moderate asthma	Phase II NCT02479412	N = 48	<p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p>	<ul style="list-style-type: none"> Forced expiratory volume in one second (FEV1) 	<ul style="list-style-type: none"> FPD: Q3 12



RDEA3170 (SURI, URAT 1 inhibitor)

Gout

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Monotherapy study in subjects with gout	Phase II NCT01927198	N = 160	<ul style="list-style-type: none"> Arm A: Placebo Arm B: RDEA3170 5 mg QD Arm C: RDEA3170 10 mg QD Arm D: RDEA3170 12.5 mg QD 	<ul style="list-style-type: none"> Efficacy and Safety at Week 24 	<ul style="list-style-type: none"> FPD: Q3 13 LPD: Q4 13 Study complete
Monotherapy study in Japanese patients with gout or asymptomatic hyperuricemia	Phase II NCT02078219	N = 200	<ul style="list-style-type: none"> Arm A: Placebo Arm B: RDEA3170 5 mg QD Arm C: RDEA3170 10 mg QD Arm D: RDEA3170 12.5 mg QD Arm E: Open-label Allopurinol 100mg BID 	<ul style="list-style-type: none"> To compare the efficacy of RDEA3170 monotherapy at Week 16 with placebo and Allopurinol. 	<ul style="list-style-type: none"> FPD: Q1 14 LPD: Q3 14 Study complete
Combination therapy study with febuxostat in subjects with gout	Phase II NCT02246673	N = 200	<ul style="list-style-type: none"> Arm A: RDEA3170 2.5 mg QD Arm B: RDEA3170 5.0 mg QD Arm C: RDEA3170 10 mg QD Arm D: RDEA3170 15 mg QD <p>*All arms include combination with 40 mg QD febuxostat for 7 days followed by combination with 80 mg QD febuxostat for 7 days</p>	<ul style="list-style-type: none"> To assess the PK and PD profiles of RDEA3170 administered with febuxostat 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: Q2 15 Est. completion: Q3 15
Combination study with febuxostat for treating gout or asymptomatic hyperuricemia in Japanese patients	Phase II NCT02317861	N = 60	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> To assess the PD and safety profiles of RDEA3170 administered with febuxostat 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: Q2 15 Est. completion: Q3 15
Combination therapy study with allopurinol in subjects with gout	Phase II NCT02498652	N = 40	<ul style="list-style-type: none"> Arm A: RDEA3170 2.5, 7.5 or 15 mg QD + 300 mg QD allopurinol Arm B: RDEA3170 5.0, 10 or 20 mg QD + 300 mg QD allopurinol Arm C: 300 mg QD or 600 mg QD allopurinol alone 	<ul style="list-style-type: none"> To assess the PK and PD profiles of RDEA3170 administered with allopurinol 	<ul style="list-style-type: none"> FPD: Q3 15 LPD: Q4 15 Est. completion: H1 16



Savolitinib (AZD6094) (MET)

Papillary renal cell and other cancers

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Papillary renal cell cancer	Phase II NCT02127710	N = 90	<ul style="list-style-type: none"> Single arm study: AZD6094 600mg QD Conducted in UK, US, Canada 	<ul style="list-style-type: none"> Overall Response Rate 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: Q3 15 Est. completion: H1 16
Advanced cancer (all-comers)	Phase I NCT01773018	N = 50	<ul style="list-style-type: none"> Dose escalation study Conducted in Australia 	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPD: Q1 12 LPD: Q3 15 Est. completion: H1 16
Advanced cancer (all comers)	Phase I NCT01985555	N = 70	<ul style="list-style-type: none"> Dose escalation study Conducted in China 	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPD: Q2 13 LPD: Q3 15 Est. completion: Q4 15
Advanced gastric cancer (all-comers)	Phase I NCT02252913	N = 50	<ul style="list-style-type: none"> Dose escalation study Conducted in China 	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: H1 16 Est. completion: H2 16



AZD1775 (WEE-1)

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

Patient population	Study phase	Number of patients	Design	Endpoints	Status
p53 mutant advanced solid tumours	Phase II NCT02482311	N = 132	<ul style="list-style-type: none"> • Monotherapy Conducted in US	<ul style="list-style-type: none"> • Progression Free Survival • Secondary endpoint: Overall Survival 	<ul style="list-style-type: none"> • FPD: Q3 15 • LPD: H1 16 • Est. completion H2 16
p53 mutant PSR ovarian cancer	Phase II NCT01357161	N = 120	<ul style="list-style-type: none"> • Arm 1: carbo/paclitaxel + AZD1775 225mg • Arm 2: carbo/paclitaxel + placebo Global study 9 countries	<ul style="list-style-type: none"> • Progression Free Survival • Secondary endpoint: Overall Survival 	<ul style="list-style-type: none"> • FPD: Q4 12 • LPD: Q3 14 • Completed Q1 15
p53 mutant PR ovarian cancer	Phase II NCT02272790	N = 177	<ul style="list-style-type: none"> • Arm 1: chemotherapy + AZD1775 225mg • Arm 2: chemotherapy Global study	<ul style="list-style-type: none"> • Progression Free Survival • Secondary endpoint: Overall Survival 	<ul style="list-style-type: none"> • FPD: Q1 15 • LPD: Q4 16 • Est. completion: 2017
Previously untreated Stage IV non-squamous NSCLC with TP53 mutations	Phase II NCT02087241	N = 22	<ul style="list-style-type: none"> • Arm 1: carboplatin + pemetrexed + AZD1775 225 mg BiD • Arm 2: carboplatin + pemetrexed + placebo Conducted in US	<ul style="list-style-type: none"> • Progression Free Survival • Secondary endpoint: Overall Survival 	<ul style="list-style-type: none"> • FPD: Q1 14 • LPD: Q2 15 • Completed: Q2 15
Previously treated NSCLC with TP53 mutations	Phase II NCT02087176	N = 48	<ul style="list-style-type: none"> • Arm 1: docetaxel + AZD1775 225 mg BiD • Arm 2: docetaxel+ placebo 20-25 patient run in for safety and efficacy Conducted in US	<ul style="list-style-type: none"> • Progression Free Survival • Secondary endpoint: Overall Survival 	<ul style="list-style-type: none"> • FPD: Q1 14 • LPD: Q2 15 • Completed: Q2 15



AZD2014 (TORC 1/2)

Breast cancer

Patient population	Study phase	Number of patients	Design	Endpoints	Status
2 nd line ER+ metastatic breast cancer	Phase II MANTA NCT02216786 Partnered*	N = 300	<ul style="list-style-type: none"> • Arm 1: Fulvestrant • Arm 2: Fulvestrant + AZD2014 50mg BD continuous dosing • Arm 3: Fulvestrant + AZD2014 125mg BD two days on, 5 off • Arm 4: Fulvestrant + everolimus <p>The study will be conducted in Europe</p>	<ul style="list-style-type: none"> • Progression Free Survival • Secondary endpoint: Overall Survival 	<ul style="list-style-type: none"> • FPD: Q2 14 • LPD: Q4 15 • Est. completion: 2017
ER+ advanced metastatic breast cancer	Phase I NCT01597388	N = 92	<ul style="list-style-type: none"> • SAD and MAD. Continuous and intermittent dosing schedules in combination with fulvestrant <p>Sites in US</p>	<ul style="list-style-type: none"> • Safety and tolerability of AZD2014 in combination with fulvestrant • Determination of steady state PK profile of AZD2014 in combination with fulvestrant 	<ul style="list-style-type: none"> • FPD: Q2 12 • LPD: Q2 15 • Est. completion: Q3 15
Relapsed or refractory squamous non-small cell lung cancer (at least one prior therapy)	Phase IIa NCT02403895	N = 40	<p>Open label</p> <p>Single arm – patient are divided in two groups Group A - intensive PK Group B – sparse PK</p> <p>Dose: intermittent AZD2014 50mg BID (3 days on + 4 days off) + weekly paclitaxel 80 mg/m²</p> <p>Multicentre: EU and US study sites</p>	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • FPD: Q2 15 • LPD: H2 16 • Est. completion: 2017

*Collaborative study. Peter Schmid PI. Sponsor QMUL



AZD3759 (EGFRm BBB)

Lung cancer with lung and/or brain metastases

Patient population	Study phase	Number of patients	Design	Endpoints	Status
EGFRm+ NSCLC	Phase I NCT02228369	N = 47	<ul style="list-style-type: none"> MAD Expansion in LM patients at RP2D with AZD3759 Expansion in LM patients at 160mg with AZD9291 Study conducted in South Korea and Taiwan	<ul style="list-style-type: none"> Safety and tolerability Preliminary anti-tumour activity 	<ul style="list-style-type: none"> FPD: Q4 14 Est. completion: H2 16



AZD4547 (FGFR)

Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Stage IIIB-IV NSCLC patients Biomarker-targeted 2L therapy	Phase II/III Lung Master Protocol NCT02154490 Partnered with NCI and SWOG	N = 318 (AZD4547 arm only)	5-Arm study based on biomarker expression <ul style="list-style-type: none"> Arm 1: MEDI4736/Unmatched biomarker IVQ2W Arm 2: AZD4547 (FGFR inhibitor) Arm 3: CDK4/6 inhibitor Arm 4: PI3K Inhibitor Arm 5: HGFR Inhibitor 	<ul style="list-style-type: none"> Progression Free Survival (PFS) Overall Survival (OS) 	<ul style="list-style-type: none"> FPD: Q4 14 Est. completion: 2022 (final data collection for primary outcome measure Ph III)
Female ER+ breast cancer patients whose disease has progressed following treatment with one prior endocrine therapy	Phase II GLOW NCT01202591	N = 40	<ul style="list-style-type: none"> Part A: AZD4547 in ascending multiple doses in combination with 25mg exemestane Part B: <ul style="list-style-type: none"> Arm 1: AZD4547 (dose from part A) + fulvestrant Arm 2: placebo + fulvestrant Patients with FGFR1 polysomy (30 patients) or FGFR1 amplification (60 patients)	<ul style="list-style-type: none"> Part A: MTD of AZD4547 in combination with 25mg exemestane in three schedules of AZD4547 Part B Interim analysis: Tumour size analysis on 30 FGFR amplified patients Part B Final analysis: Progression Free Survival 	<ul style="list-style-type: none"> LPD: Q2 14 Completed: Q1 15
Advanced gastro-oesophageal cancer	Phase II SHINE NCT01457846	N = 71	<ul style="list-style-type: none"> Arm 1 (FGFR2 polysomy): AZD4547 vs paclitaxel randomised 1:1 (30 to 80 patients) Arm 2 (FGFR 2 low gene amplification: AZD4547 vs paclitaxel randomised 3:2 (25 to 80 patients) Arm 3 (FGFR2 high gene amplification: AZD4547 vs paclitaxel randomised 3:2 (25 to 80 patients) 	<ul style="list-style-type: none"> Progression Free Survival Key Secondary: Overall survival/Tumour size 	<ul style="list-style-type: none"> Recruitment closed after interim analysis: Q2 13 Completed: Q1 15
Advanced cancer who have failed standard therapy or for whom no standard therapy exists	Phase I NCT01213160	N = 33	<ul style="list-style-type: none"> Part A: AZD4547 in ascending multiple doses given bd and od (c. 30 patients) Part B: AZD4547 in patients whose tumours have FGFR amplification (c. 8 patients) Conducted in Japan	<ul style="list-style-type: none"> Part A: MTD and Recommended dose for Parts B and C Part B: Safety and tolerability and preliminary anti-tumour activity 	<ul style="list-style-type: none"> Completed: Q2 13

AZD4547 (FGFR)

Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Advanced cancer who have failed standard therapy or for whom no standard therapy exists	Phase I NCT00979134	N = 94	<ul style="list-style-type: none"> Part A: Ascending oral doses of AZD4547 to define maximum tolerated dose (MTD) and /or continuous, tolerable recommended dose (RD) Part B: Dose expansion phase at RD defined in Part A Part C: Expansion phase in patients with FGFR1 and FGFR2 amplified tumours at the RD defined from Part A 	<ul style="list-style-type: none"> Part A: MTD and Recommended dose for Parts B and C Part B and C: Safety and tolerability, PK and preliminary anti-tumour activity 	<ul style="list-style-type: none"> Completed: Q1 14



AZD9496 (SERD)

Breast cancer

Patient population	Study phase	Number of patients	Design	Endpoints	Status
ER+ Breast Cancer	Phase I NCT02248090	N ~150	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Primary Outcome Measures: Safety and tolerability Secondary Outcome Measures: Single and multiple dose pharmacokinetics of AZD9496 4β-hydroxycholesterol concentration in blood Anti-tumour activity 	<ul style="list-style-type: none"> FPD: Q4 14 Est. completion: 2017



AZD5312 (ISIS-AR)

Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Advanced solid tumours with androgen receptor pathway as a potential factor	Phase I NCT02144051	N = 90	<p>Part A: Dose escalation</p> <ul style="list-style-type: none"> AZD5312 in ascending multiple doses given iv (c. 30 patients) <p>Part B: Dose expansion</p> <ul style="list-style-type: none"> AZD5312 at recommended dose from Part A, given iv <ul style="list-style-type: none"> Arm 1: Prostate cancer patients who have received a second generation antihormonal therapy (eg. abiraterone, enzalutamide) but have not responded (n=20). AZD5312 at RP2D Arm 2: Prostate cancer patients who have initially responded to a second generation anti-hormonal therapy, but later relapsed (n=20). Arm 3: Non-mCRPC patient population (eg. breast, bladder, ovarian) expansion, where AR pathway may be a potential factor (n=20). 	<ul style="list-style-type: none"> Part A: MTD and Recommended dose for Parts B. Safety and tolerability and preliminary anti-tumour activity Part B (prostate patients): Response rate, blood PSA, circulating tumour cell enumeration, disease progression 	<ul style="list-style-type: none"> FPD: Q2 14 Est. completion: H1 16



AZD5363 (AKT)

Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
ER+ breast cancer receiving 1 st treatment with paclitaxel in the advanced setting	Phase IIb NCT01625286	N = 100	<ul style="list-style-type: none"> Arm 1: AZD5363 + paclitaxel Arm 2: Paclitaxel alone Two strata: PIK3CA mutation positive vs Mutation not detected	<ul style="list-style-type: none"> Progression Free survival (PFS) Response rate (ORR) & overall survival are secondary endpoints 	<ul style="list-style-type: none"> FPD: Q1 14 Est. primary completion: H2 16 Est. study completion: 2017
Breast and gynaecological cancers with PIK pathway mutation	Phase I NCT01226316	N = 20 per arm	Monotherapy AZD5363 480mg BD 4 days on 3 days off <ul style="list-style-type: none"> Part C arm 1: Breast with PIK3CA mutation Part C arm 2: Gynaecological with PIK3CA mutation Part D arm 1: Breast with AKT-1 mutation Part D arm 2: Gynaecological with AKT-1 mutation Part D arm 3: other tumours with AKT-1 mutation Possible expansion up to 120 patients per arm	<ul style="list-style-type: none"> Safety and tolerability Response Rate (ORR) 	<ul style="list-style-type: none"> FPD: Q3 13 Est. primary completion: Q4 15 Part C Arms 1 & 2 completed Part D Arms 1, 2 & 3 ongoing
All-comers solid tumours	Phase I NCT01895946	N = min 12-24	<ul style="list-style-type: none"> Comparison of PK between new tablet and original capsule formulation and preliminary assessment of food effect on tablet PK AZD5363 monotherapy 480mg bd 4 days on 3 days off 12 pts for each of formulation switch and food effect 	<ul style="list-style-type: none"> PK 	<ul style="list-style-type: none"> Tablet-capsule comparison completed in Q3 14 & formulations declared comparable Food effect cohort completed in Q2 15

*Collaborative study. Peter Schmid PI. Sponsor QMUL



AZD8835 (PI3K α/δ inhibitor)

Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Women with estrogen receptor positive HER-2 negative advanced breast cancer with and without PIK3CA mutations	Phase I NCT02260661	N = 100	<p>Part A: AZD8835 single agent dose escalation</p> <p>Part B: AZD8835 single agent dose expansion</p> <p>Part C: AZD8835 in combination with fulvestrant dose escalation</p> <p>Part D: AZD8835 (at maximum tolerated dose or recommended phase II dose) in combination with fulvestrant dose expansion</p> <p>Study to be conducted in US & UK</p>	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • FPD: Q4 14 • Est. completion: 2017



AZD6738 (ATR)

Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Solid tumours	Phase I NCT02264678	N = 117	<ul style="list-style-type: none">MAD North America – 2 sites Europe – 3 sites South Korea – 1 site	<ul style="list-style-type: none">Safety and tolerabilityEfficacy	<ul style="list-style-type: none">FPD: Q4 14Est. completion: 2017



AZD8186 (PI3Kb/d)

Solid tumours

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Advanced CRPC/SqNSCLC/TNBC and patients with known PTEN-deficient tumours	Phase I NCT01884285	N = 96	<ul style="list-style-type: none"> Part A: AZD8186 monotherapy in ascending intermittent doses in 2 schedules Part B: AZD8186 monotherapy at recommended dose and schedule(s) from Part A in PTEN deficient patients with advanced cancer <p>Study conducted in Canada, US & UK</p>	<ul style="list-style-type: none"> Part A: PK, MTD and Recommended dose and schedule(s) for Part B Part B: Safety and tolerability and preliminary assessment of antitumour activity (POM) 	<ul style="list-style-type: none"> FPD: Q2 13 Est. completion: 2017



AZD9150 (STAT3)

Haematological malignancies

Patient population	Study phase	Number of patients	Design	Endpoints	Status
DLBLC	Phase III* Partnered ISIS NCT01563302	N = 55	<ul style="list-style-type: none"> Dose-escalation and dose-expansion study IV Study conducted in US	<ul style="list-style-type: none"> Safety and tolerability . Recommended phase II dose and schedule 	<ul style="list-style-type: none"> FPD: Q1 12 Est. completion: Q2 15
HCC	Phase I NCT01839604	N = 64	<ul style="list-style-type: none"> Dose-escalation and dose-expansion study IV Study conducted in Japan, Korea, Taiwan and Hong Kong	<ul style="list-style-type: none"> Safety and tolerability . Recommended phase II dose and schedule 	<ul style="list-style-type: none"> FPD: Q2 13 Est. completion: Q2 15

* clinicaltrials.gov being updated



Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
ATM-AVI (Aztreonam- Avibactam)	Healthy volunteers	Phase I NCT01689207		<ul style="list-style-type: none"> Randomised, double-blind, 3-part study in healthy young and elderly volunteers given Aztreonam and Avibactam alone and in combination 	<ul style="list-style-type: none"> Safety/tolerability Pharmacokinetics (secondary) 	<ul style="list-style-type: none"> FPD Q4 12 LPD: Q4 14 Est. completion: Q3 15
			N = 12	<ul style="list-style-type: none"> Part A: single 1 hour IV infusions 		
			N = 56	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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		



AZD5213 (Histamine H3 receptor inverse agonist)

Neuroscience

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Tourette's Disorder	Phase IIa NCT01904773	N = 18	<ul style="list-style-type: none"> Part 1: Single blind to determine tolerability and PK in adolescent age group (age ≥12 to <18). Part 2: Randomized, double-blind, six-period, three-treatment, cross-over <ul style="list-style-type: none"> Arm 1: AZD5213 low dose Arm 2: AZD5213 high dose Arm 3: Placebo <p>US only study, 9 sites</p>	<ul style="list-style-type: none"> Improvement in Total Tic Severity Score (TTS) on the Yale Global Tic Severity Scale (YGTSS) at the last day of receiving treatment. 	<ul style="list-style-type: none"> FPD: Q4 13 LPD: Q3 14 Study completed
Painful diabetic neuropathy	Phase IIa NCT01928381	N = 32	<ul style="list-style-type: none"> Part 1: Training to improve reliability to assess pain. Part 2: Randomized, double-blind, three-period, three-treatment, cross-over <ul style="list-style-type: none"> Arm 1: AZD5213 + Pregabalin Arm 2: Pregabalin Arm 3: Placebo <p>US only study, 9 sites</p>	<ul style="list-style-type: none"> Significant change on average severity of pain (BPI-DPN). 	<ul style="list-style-type: none"> FPD: Q4 13 LPD: Q4 14 Est. topline results: Q3 15



AZD8108 (NMDA)

Phase I clinical development programme

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Healthy volunteers	Phase I NCT02248818	N = 40	<ul style="list-style-type: none"> Randomized, double-blind, placebo-controlled Part 1 SAD 3 dosage-level cohorts Part 2 MAD 2 dosage-level cohorts US only study, one site	<ul style="list-style-type: none"> Safety and tolerability Additional endpoints: <ul style="list-style-type: none"> Pharmacokinetics Pharmacodynamics 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: Q3 15 Est. topline results: Q3 15



AZD4901 (NK3 Receptor Antagonist)

Phase II clinical development programme

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Polycystic ovary syndrome patients with amenorrhea or oligomenorrhea	Phase IIa NCT01872078	N = 56	<ul style="list-style-type: none"> • Arm 1: AZD4901 20 mg QD • Arm 2: AZD4901 20 mg BiD • Arm 3: AZD4901 40 mg BiD • Arm 4: placebo <p>28 day dosing period</p> <p>Study sites in US, UK, Germany</p>	<ul style="list-style-type: none"> • Change from baseline at day 7 in Luteinizing Hormone AUC(0-8) <p>Secondary endpoints:</p> <ul style="list-style-type: none"> • Change from baseline in free and total testosterone at day 7 & day 28 	<ul style="list-style-type: none"> • Completed: Q4 14



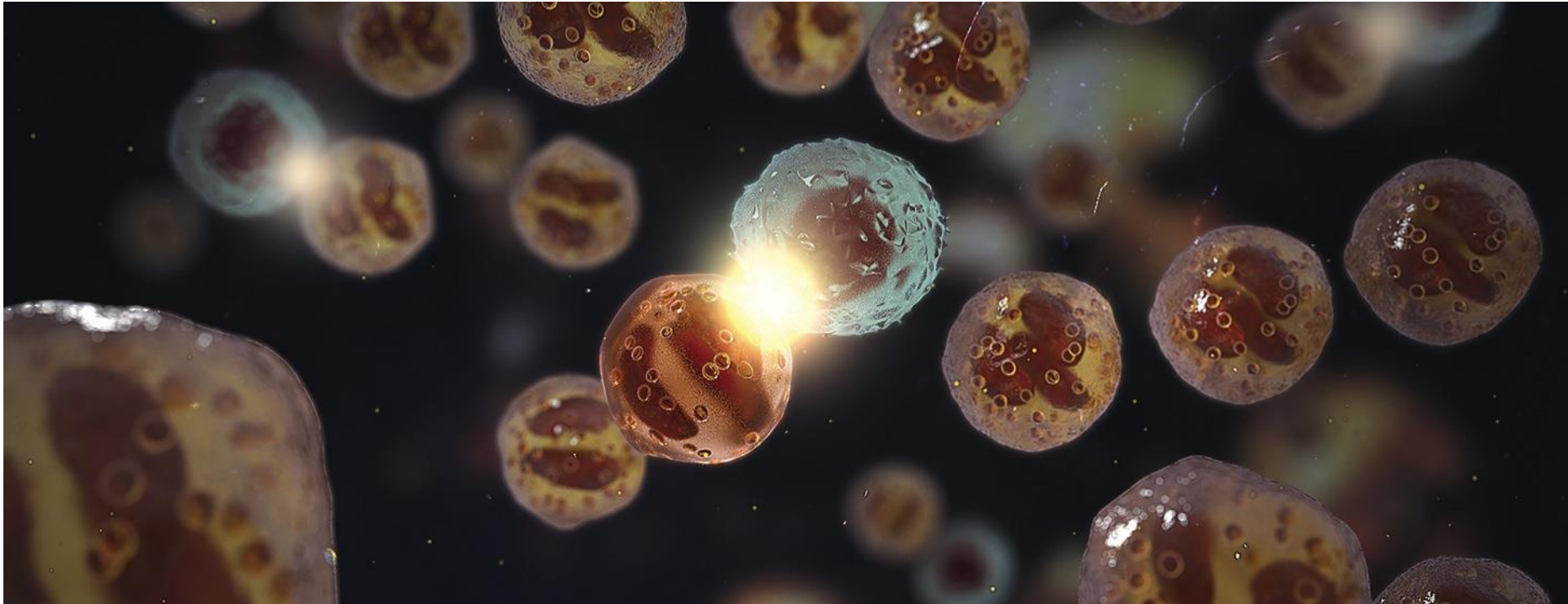
AZD3241 (MPO)

Multiple System Atrophy

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Healthy Subjects	Phase I NCT00729443	N = 46	<ul style="list-style-type: none"> • Active ArmS: SAD • Comparator Arm: placebo 1 site in Sweden	<ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs • PK 	<ul style="list-style-type: none"> • Study completed
Healthy Subjects	Phase I NCT01457807	N = 18	<ul style="list-style-type: none"> • Active ArmS: MAD • Comparator Arm: placebo 1 site in UK	<ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs • PK 	<ul style="list-style-type: none"> • Study completed
Healthy Subjects	Phase I NCT00914303	N = 59	<ul style="list-style-type: none"> • Active ArmS: MAD • Comparator Arm: placebo 1 site in Sweden	<ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs • PK 	<ul style="list-style-type: none"> • Study completed
Parkinson's Disease Patients	Phase II NCT01527695	N = 24	<ul style="list-style-type: none"> • Arm 1: AZD3241 600 mg BID for 8 weeks • Arm 2: Placebo0 Randomization 3:1 active to placebo. 3 sites in Sweden and Finland	<ul style="list-style-type: none"> • Microglia activation represented by [11C]PBR28 binding Secondary endpoints: <ul style="list-style-type: none"> • PD symptoms measured by UPDRS • Plasma MPO activity 	<ul style="list-style-type: none"> • Study completed • Poster presented at Movement Disorders Society meeting June 2014
Parkinson's Disease Patients	Phase II NCT01603069	N = 51	<ul style="list-style-type: none"> • Arm 1: AZD3241 300 mg BID for 12 weeks • Arm 2: AZD3241 600 mg BID for 12 weeks • Arm 3: Placebo Randomization 1:1:1 across arms 13 sites in US	<ul style="list-style-type: none"> • AEs, labs, vital signs, ECGs Secondary endpoints: <ul style="list-style-type: none"> • PD symptoms measured by UPDRS • Plasma MPO activity 	<ul style="list-style-type: none"> • Study completed • Poster presented at Movement Disorders Society meeting June 2014
Multiple System Atrophy (MSA)	Phase II NCT02388295	N = 54	<ul style="list-style-type: none"> • Arm 1: AZD3241 300 mg BID for 12 weeks • Arm 2: AZD3241 600 mg BID for 12 weeks • Arm 3: Placebo Randomization 1:1:1 across arms 8 sites in US 9 sites in Europe	<ul style="list-style-type: none"> • Microglia activation represented by [11C]PBR28 binding • AEs, labs, vital signs, ECGs Secondary endpoints: <ul style="list-style-type: none"> • MSA symptoms measured by UMSARS and MSA QoL • Plasma MPO activity 	<ul style="list-style-type: none"> • FPD: Q2 15 • LSD: H1 16 • Est. topline results: H2 16



Early development



Tralokinumab (IL-13 mAb)

Idiopathic Pulmonary Fibrosis (IPF)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Adults with Idiopathic Pulmonary Fibrosis	Phase II NCT01629667	N = 176	<ul style="list-style-type: none"> • Arm 1: Tralokinumab high dose 800mg IV • Arm 2: Tralokinumab low dose 400mg IV • Arm 3: Placebo IV <p>High dose: low dose: placebo (1:1:1)</p> <p>Global study – 6 countries</p>	<ul style="list-style-type: none"> • Change from baseline in percent-predicted forced vital capacity at week 52* <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • No. of patients with disease progression • Safety and tolerability • Tralokinumab serum concentration 	<ul style="list-style-type: none"> • FPD: Q4 12 • LPD: Q1 15 • Interim analysis: Q3 15 • Est. topline results: H1 16
Japanese adults with Idiopathic Pulmonary Fibrosis	Phase II NCT02036580	N = 20	<p><u>Cohort 1:</u></p> <ul style="list-style-type: none"> • Arm 1: Tralokinumab Low dose 400mg IV • Arm 2: Placebo IV <p><u>Cohort 2:</u></p> <ul style="list-style-type: none"> • Arm 1: Tralokinumab High dose 800mgIV • Arm 2: Placebo IV <p>8:2 randomisation in both cohorts Japan only study</p>	<ul style="list-style-type: none"> • Safety and tolerability <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • Tralokinumab serum concentration • Immunogenicity 	<ul style="list-style-type: none"> • FPD: Q1 14 • LPD: Q4 14 • Est. topline results: Q4 15

* As per protocol amendment, primary endpoint is modified from Change from baseline in percent-predicted forced vital capacity at Week 72 to Week 52 in April 2015



Tralokinumab (IL-13 mAb)

Atopic dermatitis

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Adults with atopic dermatitis	Phase II NCT02347176	N = 184	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Change from baseline in SCORAD at week 12 Key Secondary Endpoints: <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • FPD: Q1 15 • LPD: Q4 15 • Est. topline results: H1 16



MEDI7836 (IL-13 mAb)

Asthma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Healthy volunteers	Phase I NCT02388347	N = 32	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Safety and tolerability	<ul style="list-style-type: none">• FPD: Q1 15• LPD: Q3 15• Est. topline results: Q4 15



MEDI9929 (TSLP mAb)

Asthma

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

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Adult subjects with inadequately controlled, severe asthma	Phase II PATHWAY NCT02054130 Partnered	N = 552	<ul style="list-style-type: none">• Arm 1: Placebo• Arm 2: Low dose MEDI9929 70mg SC• Arm 3: Medium dose MEDI9929 210mg SC• Arm 4: High dose MEDI9929 280mg SC	<ul style="list-style-type: none">• Reduction in the annualized asthma exacerbation rate (AER) measured at Week 52	<ul style="list-style-type: none">• FPD: Q2 14• LPD: Q4 15• Est. topline results: H2 16



MEDI5872 (B7RP-1 mAb)

Systemic Lupus Erythematosus (SLE)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
SLE and lupus related inflammatory arthritis	Phase I NCT01683695 Partnered	N = 40	Dose escalation study: <ul style="list-style-type: none"> • Arm 1: MEDI5872 SC • Arm 2: placebo SC Global study – 8 countries	<ul style="list-style-type: none"> • Safety and tolerability • Lupus Arthritis Response Rate 	<ul style="list-style-type: none"> • FPD: Q2 12 • LPD: Q4 15 • Est. topline results: Q3 15
Primary Sjögren's syndrome	Phase IIa NCT02334306 Partnered	N = 42	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Safety and tolerability • Change in the ESSDAI score from baseline to Day 99. 	<ul style="list-style-type: none"> • FPD: Q3 15 • LPD : 2017 • Est. topline results: 2017



Mavrilimumab (GMCSF mAb)

Rheumatoid arthritis (RA)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
RA patients who have failed 1 or 2 anti-TNF for efficacy, intolerance or safety, OR Inadequate response to DMARDs	Phase II EARTH Explorer 2 NCT01715896	N = 138	<ul style="list-style-type: none"> • Arm 1: Mavrilimumab SC • Arm 2: golimumab Global study (ex-US) on MTX background; 17 countries	<ul style="list-style-type: none"> • ACR 20/50/70 at wk 24 • DAS28 remission • Function (HAQ-DI) 	<ul style="list-style-type: none"> • FPD: Q1 13 • LPD: Q3 14 • Topline results: Q4 14
Eligible RA patients from Explorer 1 & 2	Phase II EARTH Explorer X NCT01712399	N = 400	<ul style="list-style-type: none"> • Arm 1: Mavrilimumab 100mg SC Open label extension of EARTH Explorer 1 & 2 Global study (ex-US) on MTX background; 23 countries	<ul style="list-style-type: none"> • Safety and exploratory efficacy 	<ul style="list-style-type: none"> • FPD: Q1 13 • OLE, Est. topline results: Q4 15
Healthy Japanese subjects	Phase I NCT02213315	N = 24	<ul style="list-style-type: none"> • Arm 1: Mavrilimumab medium dose SC • Arm 2: Mavrilimumab high dose SC • Arm 3: Placebo SC UK Study; Japanese subjects	<ul style="list-style-type: none"> • Pharmacokinetic profile • Safety and tolerability 	<ul style="list-style-type: none"> • FPD: Q3 14 • LPD: Q3 14 • Topline results: Q4 14



Other biologics

Autoimmunity

Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
Anti-CD19 mAb (MEDI-551)	Adults with Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders (NMO/NMOSD)	Phase II/III NCT02200770	N = 212 (est.)	<ul style="list-style-type: none"> Arm 1: MEDI-551500mg IV Arm 2: placebo IV Open-label extension 300mg <p>Global study 26 Countries</p>	<ul style="list-style-type: none"> Primary: Time to attack Secondary: Attack rate, safety and tolerability 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: 2017 Est. topline results: 2018
	Adults with multiple sclerosis	Phase I NCT01585766	N = 28	<ul style="list-style-type: none"> Arm 1: 30 mg × 2 IV MEDI-551 (n = 6) or IV placebo × 2 (n = 2) Arm 2: 100 mg × 2 IV MEDI-551 (n = 3) or IV placebo × 2 (n = 1) Arm 3: 60 mg × 1 SC MEDI-551 (n = 3) or SC placebo × 1 (n = 1) Arm 4: 300 mg × 1 SC MEDI-551 (n = 3) or SC placebo × 1 (n = 1) Arm 5: 600 mg × 2 IV MEDI-551 (n = 6) or IV placebo × 2 (n = 2) <p>Global study</p>	<ul style="list-style-type: none"> Safety, PK 	<ul style="list-style-type: none"> FPD: Q3 12 LPD: Q3 14 Topline results: Q2 15
Anti-CD40L (MEDI4920)	Healthy adults	Phase I NCT02151110	N = 56	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Safety, tolerability, and pharmacokinetics, anti-drug antibody, inhibition of T-cell dependent antibody response 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: Q4 15 Topline results: H1 16



Other biologics

Cardiovascular & metabolic disease

Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
rhLCAT (MEDI6012)	Adults with stable coronary artery disease and low HDL	Phase I NCT01554800	N = 16	<ul style="list-style-type: none"> SAD IV 	<ul style="list-style-type: none"> Safety Changes in total HDL Change in Cholesteryl Ester 	<ul style="list-style-type: none"> Completed by Alphacore
rh-Factor II (MEDI8111)	Healthy male subjects	Phase I NCT01958645	N = 12	<ul style="list-style-type: none"> SAD IV administration UK study site 	<ul style="list-style-type: none"> Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, immunogenicity and physical examination 	<ul style="list-style-type: none"> FPD: Q4 13 LPD: Q4 14 Completed: Q4 14
GLP-1-Glu MEDI0382	Healthy male subjects	Phase I NCT02394314	N = 64	<ul style="list-style-type: none"> SAD SC administration Germany 	<ul style="list-style-type: none"> Safety profile in terms of adverse events (AE), vital signs, ECG, telemetry, lab variables, nausea, immunogenicity and physical examination 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: Q4 15 Est. topline results: Q3 15



Durvalumab (MEDI4736) (PD-L1 mAb) + Iressa (gefitinib) Non-small cell lung cancer (NSCLC)

Patient population	Study phase	Number of patients	Design	Endpoints	Status
NSCLC (Escalation phase) EGFR M+ NSCLC naïve to EGFR-TKI therapy (Expansion phase)	Phase I NCT02088112	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	<ul style="list-style-type: none"> • Safety • Optimal biologic dose for the combination • Secondary endpoints include tumour response (CR, PR, SD, PD), Objective response rate, disease control rate, progression-free survival, immunogenicity, pharmacokinetics, pharmacodynamics 	<ul style="list-style-type: none"> • FPD: Q2 14 • LPD: Q2 15 • Est. topline results: Q2 15 • Est. completion: 2017



Other biologics

Immuno-oncology

Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
PD-L1 (durvalumab, MEDI4736)	Solid tumours	Phase III NCT01693562	N = 907	<ul style="list-style-type: none"> Dose Escalation: 5 cohorts at Q2W and 1 cohort at Q3W Dose Expansion: 16 tumor type cohorts at the Q2W MTD defined during dose escalation; one cohort at 20mg Q4W Global study – 8 countries	<ul style="list-style-type: none"> Safety Optimal biologic dose Secondary endpoints include PK, immunogenicity and antitumor activity 	<ul style="list-style-type: none"> FPD: Q3 12 LPD: Q2 15 Est. topline results: H1 16
PD-1 (MEDI0680)	Solid tumours	Phase Ia NCT02013804	N = 78	<ul style="list-style-type: none"> Dose escalation (3+3) & expansion study Study amended to explore Q2W schedule and doses > 10mg/kg 	<ul style="list-style-type: none"> Safety and tolerability 	<ul style="list-style-type: none"> FPD: Q4 13 LPD: Q2 15 (escalation) LPD: H1 16 (expansion) Est. topline results: H2 16
PD-L1 (MEDI4736)	Myelodysplastic syndrome	Phase I NCT02117219	N = 70	Dose-escalation and dose-expansion study <ul style="list-style-type: none"> Arm 1: MEDI4736 IV Global study – 4 countries	<ul style="list-style-type: none"> Safety and tolerability Secondary endpoints include duration of response, progression free survival and overall survival 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: Q2 15 (40 pts) LPD: Q4 15 (70 pts) Est. topline results: Q4 15



Durvalumab (MEDI4736) (PD-L1 mAb) + Tabinlar (dabrafenib)/ Mekinist (trametinib) Melanoma

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Metastatic or unresectable melanoma BRAF mutation+ (Cohort A) BRAF wild type (Cohorts B&C)	Phase III NCT02027961	N = 69	Dose Escalation: <ul style="list-style-type: none"> Cohort A dabrafenib 150mg BiD/ trametinib 2mg QD/ MEDI4736 IV Cohort B trametinib 2mg QD/ MEDI4736 IV Cohort C trametinib 2mg QD/ MEDI4736 IV Dose Expansion: <ul style="list-style-type: none"> Each cohort will be expanded at the MTD to enroll a total of 20 subjects per cohort Global study – 2 countries	<ul style="list-style-type: none"> Safety Optimal biologic dose for the combination Secondary endpoints include Objective Response and Disease Control, Duration of Response, Progression-free Survival and Overall Survival, Pharmacokinetics and immunogenicity 	<ul style="list-style-type: none"> FPD: Q1 14 LPD: Q4 15 Est. topline results: 2017



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

Patient population	Study phase	Number of patients	Design	Endpoints	Status
NSCLC (Immunotx naïve and Immunotx pretreated patient cohorts)	Phase Ib NCT02000947	N = 301	<ul style="list-style-type: none"> Dose Escalation: minimum 5 cohorts exploring various treme Q4W and MEDI4736 IV Q4W dose combinations, higher dose levels and alternate Q2 schedule added with amendment Dose Expansion: MTD for the combination in escalation to be explored in expansion North American study centres, exploration of 1-2 ex-US countries for expansion	<ul style="list-style-type: none"> Safety Optimal biologic dose for the combination Secondary endpoints include Antitumour activity, PK and immunogenicity 	<ul style="list-style-type: none"> FPD: Q4 13 LPD: Q3 15 Est. topline results: 2017
Solid tumours (Basket study)	Phase I NCT02261220	N = 210	<ul style="list-style-type: none"> Dose Exploration: 2 cohorts exploring various Q4W treme and MEDI4736 dose combinations and 2 cohorts exploring various Q2W treme and MEDI4736 dose combinations Dose Expansion: MTD for the combination in escalation to be explored in expansion cohorts specific for each of 5 tumour types US-only study centres	<ul style="list-style-type: none"> Safety & tolerability Optimal biologic dose for the combination Secondary endpoints include Antitumour activity, PK/PD and immunogenicity 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: H1 16 Est. topline results: 2017
SCCHN	Phase I NCT02262741	N = 68	<ul style="list-style-type: none"> Arm A: treatment-naïve, PD-L1+, combo Arm B: treatment-naïve, PD-L1-, combo Arm C: PD1/PDL1 refractory, combo North American study centres	<ul style="list-style-type: none"> Safety & tolerability Secondary endpoints include OR, DC, DoR, PFS, OS, PK/PD, immunogenicity and biomarkers 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: H1 16 Est. topline results: 2017
Gastric or GEJ adenocarcinoma	Phase Ib/II NCT02340975	N = 174	<ul style="list-style-type: none"> Arm A: durvalumab + tremelimumab 2L Arm B: durvalumab 2L Arm C: tremelimumab 2L Arm D: durvalumab + tremelimumab 3L US-only study centres	<ul style="list-style-type: none"> Safety & tolerability, ORR, PFS Secondary endpoints include DCR, OS, DoR, PD-L1 Expression 	<ul style="list-style-type: none"> FPD: Q2 15 LPD: H1 16 Est. topline results: 2018



MEDI6469 (murine OX40 mAb) + combinations

Advanced malignancies

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Advanced malignancies	Phase I/II NCT02205333	N = 212	<p>Dose-escalation phase</p> <ul style="list-style-type: none"> MEDI6469 IV monotherapy MEDI6469 IV + MEDI4736 IV MEDI6469 IV + tremelimumab IV MEDI6469 IV + rituximab IV <p>Dose-expansion phase at selected dose from dose-escalation phase</p> <ul style="list-style-type: none"> MEDI6469 IV + MEDI4736 IV MEDI6469 IV + tremelimumab IV MEDI6469 IV + rituximab IV <p>US-only study centres</p>	<ul style="list-style-type: none"> Determination of MTD Safety Secondary endpoints include antitumour activity, pharmacokinetics, and immunogenicity 	<ul style="list-style-type: none"> FPD: Q3 14 LPD: H2 16 Est. topline results: 2017



MEDI0562 (OX40 agonist)

Advanced malignancies

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Advanced malignancies	Phase I NCT02318394	N = 50	Dose-escalation phase <ul style="list-style-type: none"> MEDI0562 IV Dose-expansion phase <ul style="list-style-type: none"> MEDI0562 IV recommended dose US-only study centres 	<ul style="list-style-type: none"> Safety Determination of MTD Secondary endpoints include preliminary antitumor activity, pharmacokinetics, biomarker activity, and immunogenicity 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: H2 16 Est. topline results: 2017



MEDI6383 (OX40 agonist) + Durvalumab (MEDI4736; PD-L1 mAb)

Advanced malignancies

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Advanced malignancies	Phase I NCT02221960	N = 212	Dose-escalation phase <ul style="list-style-type: none"> MEDI6383 IV MEDI6383 IV + MEDI4736 IV Dose—expansion phase <ul style="list-style-type: none"> MEDI6383 IV recommended dose MEDI6383 IV + MEDI4736 IV recommended dose US-only study centres	<ul style="list-style-type: none"> Safety Determination of MTD <ul style="list-style-type: none"> Secondary endpoints include preliminary antitumour activity, pharmacokinetics, Biomarker activity, and immunogenicity 	<ul style="list-style-type: none"> FPD: Q2 15 LPD: H2 16 Est. topline results: 2017



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

Advanced malignancies

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Advanced malignancies	Phase I NCT02118337	N = 150	Dose-escalation phase <ul style="list-style-type: none"> MEDI4736 IV + MEDI0680 IV Dose-expansion phase at selected dose from dose-escalation phase <ul style="list-style-type: none"> MEDI4736 IV + MEDI0680 IV recommended dose 	<ul style="list-style-type: none"> Safety Determination of MTD Secondary endpoints include tumour response such as objective response rate, disease control rate, progression-free survival, duration of response, overall survival, immunogenicity, pharmacokinetics, pharmacodynamics 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: Q3 15 Est. topline results: 2017



MEDI0562 (OX40 agonist)

Advanced malignancies

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Advanced malignancies	Phase I NCT02318394	N = 50	Dose-escalation phase <ul style="list-style-type: none"> MEDI0562 IV Dose-expansion phase <ul style="list-style-type: none"> MEDI0562 IV recommended dose US-only study centres 	<ul style="list-style-type: none"> Safety Determination of MTD Secondary endpoints include preliminary antitumor activity, pharmacokinetics, biomarker activity, and immunogenicity 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: H2 16 Est. topline results: 2017



MEDI-551 (CD19 mAb)

Haematological malignancies

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Adults with relapsed or refractory B-cell chronic lymphocytic leukemia (CLL)	Phase II NCT01466153	N = 180	<ul style="list-style-type: none"> Arm 1: MEDI-551 IV (dose-level 1) and Bendamustine Arm 2: MEDI-551 IV (dose-level 2) and Bendamustine Arm 3: Rituxan and Bendamustine Open-label study	<ul style="list-style-type: none"> ORR, including Complete Response (CR) or Partial Response (PR) 	<ul style="list-style-type: none"> FPD: Q1 12 LPD: Q3 14 Est. topline results: H1 16
Adults with relapsed or refractory B-cell diffuse large B-cell lymphoma (DLBCL)	Phase II NCT01453205	N = 170	<ul style="list-style-type: none"> Arm 1: MEDI-551 dose level 1 and ICE/DHAP Arm 2: MEDI-551 dose level 2 and ICE/DHAP Arm 2: Rituxan + ICE/DHAP Open-label study	<ul style="list-style-type: none"> ORR, including Complete Response (CR) or Partial Response (PR) 	<ul style="list-style-type: none"> FPD: Q1 12 LPD: H1 16 Est. topline results: 2018
Adults with relapsed or refractory B-cell malignancies	Phase I/II NCT00983619	N = 193	<ul style="list-style-type: none"> Arm A: MEDI-551 IV dose escalation study and expansion (FL/CLL/DLBCL/MM) Arm B: Medi-551 IV dose escalation and expansion (CLL) Arm C: MEDI-551 IV dose escalation and expansion with Rituximab (DLBCL) Arm D: MEDI-551 IV (CD20 refractory DLBCL) 	<ul style="list-style-type: none"> MTD and efficacy Safety and tolerability Clinical activity of MEDI-551 	<ul style="list-style-type: none"> FPD: Q2 10 (Arm A) FPD: Q2 14 (Amended Arms B – D) LPD: 2017 Est. topline results: 2017
Adults with relapsed/refractory aggressive B-cell lymphomas	Phase I/II NCT02271945	N = 38	<ul style="list-style-type: none"> MEDI-551 and MEDI0680 (AMP-514) IV Open-label study	<ul style="list-style-type: none"> MTD and efficacy Safety and tolerability Clinical activity of MEDI-551 in combination with MEDI0680 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: 2017 Est. topline results: 2019
Adults with relapsed or refractory B-cell malignancies	Phase I NCT01957579	N = 18	<ul style="list-style-type: none"> Dose-escalation study IV Conducted in Japan	<ul style="list-style-type: none"> MTD and efficacy 	<ul style="list-style-type: none"> FPD: Q2 11 LPD: Q3 15 Est. topline results: H2 16



Moxetumomab Pasudotox (CD22 mAb)

Haematological malignancies

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Adults with relapsed or refractory hairy cell leukemia	Phase III NCT01829711	N = 77	<ul style="list-style-type: none"> Multicentre, single-arm, open-label study 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FPD: Q2 13 LPD: H2 16 Est. topline results: 2017
Pediatrics with relapsed or refractory pALL or lymphoblastic lymphoma of B-cell origin	Phase II NCT02227108	N = 76	<ul style="list-style-type: none"> Multicentre, single-arm, open-label study 	<ul style="list-style-type: none"> Primary: CRc rate (CR + CRi) Efficacy: MRD negative CRc rate, ORR (CR, CRi, PR), rate of eligibility for stem cell transplant, DCOR, DOR, PFS and OS Safety and tolerability Evaluate PK 	<ul style="list-style-type: none"> FPD: Q3 14 LPD: H1 16 Est. topline results: 2017
Adults with relapsed refractory HCL	Phase I NCT00586924	N = 49	<ul style="list-style-type: none"> Open Label dose escalation study 	<ul style="list-style-type: none"> MTD and efficacy 	<ul style="list-style-type: none"> FPD: Q2 07 LPD: Q1 14 Topline results : Q1 15
Children, adolescents and young adults with refractory ALL or NHL	Phase I NCT00659425	N = 55	<ul style="list-style-type: none"> Multicentre, dose escalation study 	<ul style="list-style-type: none"> To estimate MTCD To characterize tolerability and safety profile To study clinical PK To observe anti-tumor activity 	<ul style="list-style-type: none"> FPD: Q3 08 LPD: Q2 14 Est. completion: Q4 15



Other biologics

Solid tumours

Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
Anti-IGF ligand mAb (MEDI-573)	Patients with HR+ HER2-, 1L, metastatic breast cancer taking aromatase inhibitors	Phase III NCT01446159	N = 176	<ul style="list-style-type: none"> Arm 1: MEDI-573 IV and Aromatase Inhibitor Arm 2: Aromatase Inhibitor alone Open label study	<ul style="list-style-type: none"> Progression Free Survival Retrospective evaluation of predictive biomarker +ve subgroups 	<ul style="list-style-type: none"> FPD: Q2 12 LPD: Q2 13 Est. topline results: 2018
Anti-Ang2 mAb (MEDI3617)	Solid tumours and ovarian cancer	Phase I NCT01248949	N = 25	• MEDI3617 Dose Escalation	• Safety and tolerability	<ul style="list-style-type: none"> FPD: Q4 10 LPD: Q2 15 Est. topline results: H1 16
			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	<ul style="list-style-type: none"> MEDI3617 + bevacizumab dose expansion in recurrent malignant glioma US-only study centres 		



Other biologics

Solid tumours

Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
Anti-CEA BiTE mAb (MEDI-565)	Adults with gastrointestinal (GI) adenocarcinoma with no available standard or curative treatments. Refractory pancreatic, colorectal and gastro-esophageal cancers	Phase I NCT01284231 Partnered	N = 51 max N = 60 max, 20 in each cohort	<ul style="list-style-type: none"> Dose-escalation (3+3), IV Dose expansion study, IV 	<ul style="list-style-type: none"> MTD and safety profile 	<ul style="list-style-type: none"> FPD: Q1 11 LPD Q3 14 Est. topline results: Q4 15
Anti-DLL4 mAb (MEDI0639)	Adults with advanced solid tumours including SCLC	Phase I NCT01577745	N = up to 28	<ul style="list-style-type: none"> Dose-escalation study (3+3); IV 	<ul style="list-style-type: none"> MTD and safety profile 	<ul style="list-style-type: none"> FPD: Q2 12 LPD: Q2 15 Est. topline results: H2 16



Other biologics

Infections

Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
Anti-Staph AT (MEDI4893)	Intubated ICU	Phase II EudraCT 2014-001097-34	N = 462	<ul style="list-style-type: none"> Placebo-controlled, single-dose, dose-ranging Route of administration: intravenous 	<ul style="list-style-type: none"> Efficacy and Safety 	<ul style="list-style-type: none"> FPD: Q4 14 LPD: H2 16 Est. topline results: 2017
RSV sF+GLA-SE (MEDI7510)	Adults ≥ 60 yrs	Phase Ia NCT02115815	N = 144	<ul style="list-style-type: none"> Double blind, randomized, placebo and active controlled cohort escalation study Route of administration: intramuscular 	<ul style="list-style-type: none"> Safety and tolerability Humoral and cell-mediated immune responses 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: Q2 14 Topline results: Q3 14
		Phase Ib NCT02289820	N = 264			
Anti-RSV mAb-YTE (MEDI8897)	Healthy adults	Phase Ia NCT02114268	N = 136	<ul style="list-style-type: none"> Arm 1: MEDI8897 IV & IM Arm 2: Placebo 	<ul style="list-style-type: none"> Evaluate Safety, Tolerability, PK and ADA 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: Q2 14 Topline results: Q2 15
	32-35 WK GA infants	Phase Ib/Ia NCT02290340	N = 90	<ul style="list-style-type: none"> Arm 1: MEDI8897 IM Arm 2: Placebo 	<ul style="list-style-type: none"> Evaluate Safety, Tolerability, PK and ADA 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: Q3 15 Est. topline results: H1 16
Anti-Pseudomonas a. mAb (MEDI3902)	Healthy adults	Phase I NCT02255760	N = 56	<ul style="list-style-type: none"> Randomized, Double-blind, Placebo-Controlled, Dose-Escalation Study Route of administration: intravenous 	<ul style="list-style-type: none"> Evaluate the Safety, Tolerability, and Pharmacokinetics 	<ul style="list-style-type: none"> FPD: Q3 14 LPD: Q1 15 Topline results: Q2 15
Anti-influenza A mAb (MEDI8852)	Healthy adults	Phase I NCT02350751	N = 40	<ul style="list-style-type: none"> Randomized, Double-blind, Placebo-Controlled, Dose-Escalation Study Route of administration: intravenous 	<ul style="list-style-type: none"> Evaluate the Safety, Tolerability, and Pharmacokinetics 	<ul style="list-style-type: none"> FPD: Q1 15 LPD: Q1 15 Topline results: Q2 15



Vaccine biologics

Influenza vaccines

Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
MEDI3250 <i>FluMist</i>	Children 2 to 6 years of age	Phase III NCT02269488	N = 100	<ul style="list-style-type: none">Open-labelRoute of administration: intranasal	<ul style="list-style-type: none">Safety and tolerability	<ul style="list-style-type: none">FPD: Q4 14LPD: Q1 15Est. topline results: Q3 15
MEDI3250 <i>FluMist</i>	Children 7 through 18 years of age	Phase III NCT02269475	N = 1,008	<ul style="list-style-type: none">Randomize, double-blind placebo-controlledRoute of administration: intranasal	<ul style="list-style-type: none">Efficacy assessed by incidence of laboratory-confirmed influenza-like illness in the two treatment armsSafety and tolerability	<ul style="list-style-type: none">FPD: Q4 14LPD: Q4 14Est. topline results: Q3 15



MEDI1814 (amyloid beta mAb)

Alzheimer's disease

Patient population	Study phase	Number of patients	Design	Endpoints	Status
Alzheimer's disease & healthy elderly	Phase I NCT02036645	N = 121	<ul style="list-style-type: none"> SAD & MAD Up to 10 iv cohorts are planned vs placebo 2 SC cohorts are planned vs placebo US only	<ul style="list-style-type: none"> Safety, tolerability 	<ul style="list-style-type: none"> FPD: Q2 14 LPD: H2 16 Est. topline results: 2017



Other biologics

Gastrointestinal

Compound	Patient population	Study phase	Number of patients	Design	Endpoints	Status
Anti- $\alpha 4\beta 7$ mAb (MEDI7183)	Moderate to severe ulcerative colitis	Phase II NCT01694485 Partnered	N = 359	<ul style="list-style-type: none"> Arm 1: MEDI7183 dose level 1, SC Arm 2: MEDI7183 dose level 2, SC Arm 3: MEDI7183 dose level 3, SC Arm 4: MEDI7183 dose level 4, SC Arm 5: Matching Placebo, SC Global study - 19 countries	<ul style="list-style-type: none"> Remission at week 8 (Mayo Score) 	<ul style="list-style-type: none"> FPD: Q4 12 LPD: Q4 14 Est. topline results: Q4 15
	Moderate to severe Crohn's disease	Phase II NCT01696396 Partnered	N = 252	<ul style="list-style-type: none"> Arm 1: MEDI7183 low dose, SC Arm 2: MEDI7183 medium dose, SC Arm 3: MEDI7183 high dose, SC Arm 4: Matching Placebo, SC Global study - 12 countries	<ul style="list-style-type: none"> Remission at week 8 (CDAI < 150) 	<ul style="list-style-type: none"> FPD: Q4 12 LPD: Q4 14 Topline results: Q2 15
	Japanese subjects with moderate to severe ulcerative colitis	Phase II NCT01959165 Partnered	N = 48	<ul style="list-style-type: none"> Arm 1: MEDI7183 low dose, 21mg SC Arm 2: MEDI7183 medium dose, 70mg SC Arm 3: MEDI7183 high dose, 210mg SC Arm 4: Matching Placebo, SC 	<ul style="list-style-type: none"> Remission at week 8 (Mayo Score) 	<ul style="list-style-type: none"> FPD: Q4 13 LPD: Q2 15 Est. topline results: Q3 15
Anti-IL-23 mAb MEDI2070	Patients with moderate to severe Crohn's disease	Phase II NCT01714726 Partnered	N = 121	<ul style="list-style-type: none"> Arm 1: MEDI2070, 700mg IV (210mg SC for OLE) Arm 2: Placebo, IV Global study - 9 countries	<ul style="list-style-type: none"> CDAI response at Week 8 defined by either a CDAI score of < 150 or a CDAI reduction from baseline of at least 100 points 	<ul style="list-style-type: none"> FPD: Q1 13 LPD: Q1 14 Topline results: Q2 14

