

ASTRAZENECA DEVELOPMENT PIPELINE, 30 SEPTEMBER 2014

Phase III / Pivotal / Registration

NMEs and significant additional indications

Submission dates shown for assets in Phase III and beyond. As disclosure of compound information is balanced by the business need to maintain confidentiality, information in relation to some compounds listed here has not been disclosed at this time.

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Cardiovascular and Metabolism							
<i>Brilinta / Brilique</i> [†]	ADP receptor antagonist	arterial thrombosis		Launched	Launched	Filed	Launched
<i>Epanova</i> [#]	omega-3 free fatty acids	hypertriglyceridaemia		Approved			
<i>Farxiga / Forxiga</i> ²	SGLT-2 inhibitor	type 2 diabetes		Launched	Launched	Launched	Filed
<i>Myalept</i>	leptin analogue	lipodystrophy		Launched	2015	N/A	
roxadustat [#]	hypoxia-inducible factor inhibitor	anaemia in CKD / ESRD	Q3 2014	2018	N/A	N/A	2016
Oncology							
AZD9291	EGFR tyrosine kinase inhibitor	advanced EGFRm T790M NSCLC	Q2 2014	2015	2015	2015	2017
<i>Caprelsa</i>	VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	medullary thyroid cancer		Launched	Launched	Q4 2014	Filed
MEDI4736 [#] PACIFIC	anti-PD-L1 MAb	stage III NSCLC	Q2 2014	2017	2020	2020	
MEDI4736 [#] ATLANTIC [†]	anti-PD-L1 MAb	3rd line NSCLC	Q1 2014	2016	2017	2017	
moxetumomab pasudotox [#]	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	2018	2018		
<i>Lynparza</i> (olaparib)	PARP inhibitor	BRCAm PSR ovarian cancer		Filed	Filed ^{7#}		
<i>Lynparza</i> (olaparib) SOLO-1	PARP inhibitor	1st line BRCAm ovarian cancer	Q3 2013	2017	2017	2017	2018
<i>Lynparza</i> (olaparib) SOLO-2	PARP inhibitor	BRCAm PSR ovarian cancer	Q3 2013	2016	2016	2016	2016
<i>Lynparza</i> (olaparib)GOLD	PARP inhibitor	2nd line gastric cancer	Q3 2013			2017	2018
<i>Lynparza</i> (olaparib) OlympiA	PARP inhibitor	adjuvant breast cancer	Q2 2014	2020	2020	2020	2021
<i>Lynparza</i> (olaparib) OlympiAD	PARP inhibitor	metastatic breast cancer	Q2 2014	2016	2016	2016	
selumetinib [#] SELECT-1	MEK inhibitor	2nd line KRAS+ NSCLC	Q4 2013	2017	2017		
selumetinib [#] ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	2017	2017		
selumetinib [#] SUMIT	MEK inhibitor	uveal melanoma	Q2 2014	2015	2015		
tremelimumab [†]	anti-CTLA-4 MAb	mesothelioma	Q2 2014	2016	2016	2016	

Phase III / Pivotal / Registration (continued)

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Respiratory, Inflammation and Autoimmunity							
benralizumab [#] CALIMA SIROCCO ZONDA	anti-IL-5R MAb	severe asthma	Q4 2013	2016	2016		
benralizumab [#] TERRANOVA GALATHEA	anti-IL-5R MAb	COPD	Q3 2014 ⁴	2018	2018		
brodalumab [#] AMAGINE-1,2,3	anti-IL-17R MAb	psoriasis	Q3 2012	++	++		
brodalumab [#] AMVISION-1,2	anti-IL-17R MAb	psoriatic arthritis	Q1 2014	++	++		
Lesinurad ³ CLEAR 1,2 CRYSTAL	selective uric acid reabsorption inhibitor (SURI)	chronic treatment of patients with gout	Q4 2011	Q4 2014	Q4 2014		
PT003 GFF	LAMA / LABA	COPD	Q2 2013	2015	2016	2017	2017
PT001 GP	LAMA	COPD	Q2 2013	2016	2016	2017	2017
tralokinumab STRATOS 1,2 TROPOS	anti-IL-13 MAb	severe asthma	Q3 2014	2018	2018	2018	
Infection							
CAZ AVI ^{#4} RECLAIM	cephalosporin / beta lactamase inhibitor	serious infections	Q1 2012	N/A	2015		2016
CAZ AVI ^{#4} REPROVE	cephalosporin / beta lactamase inhibitor	hospital-acquired pneumonia / ventilator-associated pneumonia	Q2 2013	N/A	2017		2018
Zinforo [#]	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia / skin infections		N/A	Launched	N/A	Filed
Neuroscience							
Movantik / Moventig ^{5#}	oral peripherally-acting mu-opioid receptor antagonist	opioid-induced constipation		Approved	Filed ⁶		

Partnered product.

† Registrational Phase II / III study.

++ Filing is the responsibility of the partner.

1 Brilinta in the US; Brilique in rest of world.

2 Farxiga in the US; Forxiga in rest of world.

3 Regulatory approval no longer being sought in China. This market will be served by RDEA3170.

4 No current plan to launch CAZ AVI in Japan.

5 Movantik in the US; Moventig in EU.

6 Positive opinion received.

7 Positive opinion announced on 24 October 2014.

Phases I and II

NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	Estimated Filing			
					US	EU	Japan	China
Cardiovascular and Metabolism								
tenapanor (AZD1722) [#]	NHE3 inhibitor	ESRD-Pi / CKD with T2DM ¹	II	Q1 2013				
AZD4901	hormone modulator	polycystic ovarian syndrome	II	Q2 2013				
AZD1979	melanin-concentrating hormone (MCH) receptor	obesity	I	Q2 2014				
MEDI6012	LCAT	ACS	I	Q1 2012				
MEDI8111	Rh-factor II	trauma / bleeding	I	Q1 2014				
Oncology								
AZD1775 [#]	WEE-1 inhibitor	ovarian cancer	II	Q4 2012				
AZD2014	mTOR serine / threonine kinase inhibitor	solid tumours	II	Q1 2013				
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	Q4 2011				
MEDI-551 [#]	anti-CD19 MAb	CLL / DLBCL	II	Q1 2012				
MEDI-573 [#]	anti-IGF MAb	metastatic breast cancer	II	Q2 2012				
<i>Lynparza</i> (olaparib)	PARP inhibitor	prostate cancer	II	Q3 2014				
selumetinib [#]	MEK inhibitor	2nd line KRAS-NSCLC	II	Q1 2013				
AZD5363 [#]	AKT kinase inhibitor	breast cancer	II	Q1 2014				
MEDI4736 [#]	anti-PD-L1 MAb	solid tumours	II	Q3 2014				
moxetumomab pasudotox [#]	anti-CD22 recombinant immunotoxin	pALL	II	Q3 2014				
volitinib [#]	MET tyrosine kinase inhibitor	papillary renal cell carcinoma	II	Q2 2014				
AZD5312 [#]	androgen receptor inhibitor	solid tumours	I	Q2 2014				
AZD6738	ATR serine / threonine kinase inhibitor	solid tumours	I	Q4 2013				
AZD8186	PI3 kinase beta inhibitor	solid tumours	I	Q2 2013				
AZD9150 [#]	STAT3 inhibitor	haematological malignancies	I	Q1 2012				
AZD9291 + (MEDI4736 [#] or selumetinib [#] or volitinib [#])	EGFR tyrosine kinase inhibitor + (anti-PD-L1 or MEK inhibitor or MET tyrosine kinase inhibitor)	advanced EGFRm NSCLC	I	Q3 2014				

Phases I and II (continued)

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	Estimated Filing			
					US	EU	Japan	China
Oncology (continued)								
MEDI4736 [#] after (AZD9291 or <i>Iressa</i> or (selumetinib [#] + docetaxel) or tremelimumab) TATTON	anti-PD-L1 MAb + (EGFR tyrosine kinase inhibitor or MEK inhibitor or anti-CTLA-4 MAb)	NSCLC	I	Q3 2014				
MEDI-565 [#]	anti-CEA BiTE MAb	solid tumours	I	Q1 2011				
MEDI0639 [#]	anti-DLL-4 MAb	solid tumours	I	Q2 2012				
MEDI0680	anti-PD-1 MAb	solid tumours	I	Q4 2013				
MEDI3617 [#]	anti-ANG-2 MAb	solid tumours	I	Q4 2010				
MEDI4736 [#]	anti-PD-L1 MAb	various cancers	I	Q3 2014				
MEDI4736 [#] + MEDI0680	anti-PD-L1 MAb + anti-PD-1 MAb	solid tumours	I	Q2 2014				
MEDI4736 [#] + MEDI6469	anti-PD-L1 MAb + murine OX40 agonist	solid tumours	I	Q3 2014				
MEDI4736 [#] + dabrafenib + trametinib ²	anti-PD-L1 MAb + BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014				
MEDI4736 [#] + <i>Iressa</i>	anti-PD-L1 MAb + EGFR tyrosine kinase inhibitor	NSCLC	I	Q2 2014				
MEDI4736 [#] + tremelimumab	anti-PD-L1 MAb + anti-CTLA-4 MAb	solid tumors	I	Q4 2013				
MEDI-551 [#] + rituximab ³	anti-CD19 MAb + anti-CD20 MAb	haematological malignancies	I	Q2 2014				
MEDI6383	OX40 agonist	solid tumours	I	Q3 2014				
MEDI6469 [#]	murine OX40 agonist	solid tumours	I	Q1 2006				
Respiratory, Inflammation and Autoimmunity								
AZD2115 [#]	MABA	COPD	II	Q2 2012				
AZD9412 [#]	inhaled interferon β	asthma / COPD	II	Q1 2010				
anifrolumab [#]	anti-IFN-alpha R MAb	SLE	II	Q1 2012				
brodalumab [#]	anti-IL-17R MAb	asthma	II	Q2 2013				
mavrilimumab [#]	anti-GM-CSFR MAb	rheumatoid arthritis	II	Q1 2010				
MEDI2070 [#]	anti-IL-23 MAb	Crohn's disease	II	Q1 2013				
MEDI7183 [#]	anti-a4b7 MAb	Crohn's disease / ulcerative colitis	II	Q4 2012				
MEDI9929 [#]	anti-TSLP MAb	asthma	II	Q2 2014				
PT010	LAMA / LABA / ICS	COPD	II	Q2 2014				
RDEA3170	selective uric acid reabsorption inhibitor (SURI)	chronic management of hyperuricaemia in patients with gout	II	Q3 2013				
sifalimumab [#]	anti-IFN-alpha MAb	SLE	II	Q3 2008				
tralokinumab	anti-IL-13 MAb	IPF	II	Q4 2012				

Phases I and II (continued)

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	Estimated Filing			
					US	EU	Japan	China
Respiratory, Inflammation and Autoimmunity (continued)								
AZD1419 [#]	TLR9 agonist	asthma	I	Q3 2013				
AZD7594	inhaled SGRM	asthma / COPD	I	Q3 2012 ⁴				
AZD7624	inhaled P38 inhibitor	COPD	I	Q1 2013				
MEDI-551 [#]	anti-CD19 MAb	multiple sclerosis	I	Q3 2012				
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014				
MEDI5872 [#]	anti-B7RP1 MAb	SLE	I	Q4 2008				
Infection								
AZD5847	oxazolidinone anti-bacterial inhibitor	tuberculosis	II	Q4 2012				
CXL [#]	beta lactamase inhibitor / cephalosporin	MRSA	II	Q4 2010				
ATM AVI	monobactam / beta lactamase inhibitor	targeted serious bacterial infections	I	Q4 2012				
AZD0914	GyrAR	serious bacterial infections	I	Q4 2013				
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis	I	Q2 2006				
MEDI-559	paediatric RSV vaccine	RSV prophylaxis	I	Q4 2008				
MEDI4893	MAb binding to <i>S. aureus</i> toxin	hospital-acquired pneumonia / serious <i>S. aureus</i> infection	I	Q1 2013				
MEDI3902	anti-Psl/PcrV	pseudomonas	I	Q3 2014				
MEDI7510	RSV sF+GLA-SE	prevention of RSV disease in older adults	I	Q2 2014				
MEDI8897 [#]	anti-RSV MAb-YTE	passive RSV prophylaxis	I	Q2 2014				
Neuroscience								
AZD3241	myeloperoxidase inhibitor	multiple system atrophy ⁵	II	Q2 2012				
AZD5213	histamine-3 receptor antagonist	Tourette's syndrome / neuropathic pain	II	Q4 2013				
AZD3293 [#]	beta-secretase inhibitor	Alzheimer's disease	I	Q4 2012				
AZD6423	NMDA antagonist	suicidal ideation	I	Q3 2013				
MEDI1814	anti-amyloid beta MAb	Alzheimer's disease	I	Q2 2014				

[#] Partnered product.

1 Fluid retention indication for tenapanor terminated in Q2 2014.

2 MedImmune-sponsored study in collaboration with GSK.

3 MedImmune-sponsored study in collaboration with Genentech.

4 Original programme terminated in 2013. Programme now reinitiated.

5 Multiple system atrophy is now the lead indication for this molecule.

6 Approval announced on 30 October 2014.

Line Extensions

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Cardiovascular and Metabolism							
<i>Brilinta / Brilique</i> ¹ EUCLID	ADP receptor antagonist	outcomes study in patients with peripheral artery disease	Q4 2012	2017	2017	2017	2018
<i>Brilinta / Brilique</i> ¹ PEGASUS-TIMI 54	ADP receptor antagonist	outcomes study in patients with prior myocardial infarction	Q4 2010	2015	2015	2015	2017
<i>Brilinta / Brilique</i> ¹ SOCRATES	ADP receptor antagonist	outcomes study in patients with stroke or TIA	Q1 2014	2016	2016	2016	2017
<i>Brilinta / Brilique</i> ¹ THEMIS	ADP receptor antagonist	outcomes study in patients with type 2 diabetes and CAD, but without a previous history of MI or stroke	Q1 2014	2017	2017	2018	2018
<i>Bydureon Dual Chamber Pen</i>	GLP-1 receptor agonist	type 2 diabetes		Launched	Approved	Filed	
<i>Bydureon EXSCEL</i>	GLP-1 receptor agonist	type 2 diabetes outcomes study	Q2 2010	2018	2018	2018	
<i>Bydureon weekly suspension</i>	GLP-1 receptor agonist	type 2 diabetes	Q1 2013	2015	2015		
<i>Farxiga / Forxiga</i> ² DECLARE-TIMI 58	SGLT-2 inhibitor	type 2 diabetes outcomes study	Q2 2013	2020	2020		
<i>Kombiglyze XR FDC / Komboglyze FDC</i> ³	DPP-4 inhibitor / metformin FDC	type 2 diabetes		Launched	Launched		Filed
<i>Onglyza SAVOR-TIMI 53</i>	DPP-4 inhibitor	type 2 diabetes outcomes study	Q2 2010	Filed	Launched		2015
saxagliptin / dapagliflozin FDC	DPP-4 inhibitor / SGLT-2 inhibitor FDC	type 2 diabetes	Q2 2012	2015	2015		
<i>Xigduo XR FDC / Xigduo FDC</i> ⁴	SGLT-2 inhibitor / metformin FDC	type 2 diabetes		Approved ⁶	Launched		
Oncology							
<i>Caprelsa</i>	VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	differentiated thyroid cancer	Q2 2013	2016	2016	2016	
<i>Faslodex FALCON</i>	oestrogen receptor antagonist	1st line hormone receptor +ve advanced breast cancer	Q4 2012	2016	2016	2016	2016
Respiratory, Inflammation and Autoimmunity							
<i>Symbicort</i> ⁵	ICS / LABA	Breath Actuated Inhaler asthma / COPD					

Line Extensions (continued)

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Neuroscience							
<i>Diprivan</i> [#]	sedative and anaesthetic	conscious sedation		N/A	Launched	Q4 2014	Launched
Gastrointestinal							
<i>Entocort</i>	glucocorticoid steroid	Crohn's disease / ulcerative colitis		Launched	Launched	2015	N/A
linaclotide [#]	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)		N/A	N/A	N/A	2015
<i>Nexium</i>	proton pump inhibitor	refractory reflux esophagitis		N/A	N/A	Q4 2014	N/A
<i>Nexium</i>	proton pump inhibitor	stress ulcer prophylaxis		N/A	N/A	N/A	2017
<i>Nexium</i>	proton pump inhibitor	paediatrics		Launched	Launched	2016	TBD

Partnered product.

1 *Brilinta* in the US; *Brilique* in rest of world.

2 *Farxiga* in the US; *Forxiga* in rest of world.

3 *Kombiglyze XR* in the US; *Komboglyze FDC* in the EU.

4 *Xigduo XR FDC* in the US; *Xigduo FDC* in the EU.

5 Development of a new BAI device is ongoing.

Completed projects

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
<i>Nexium</i>	proton pump inhibitor	peptic ulcer bleeding		Launched	Launched	N/A	Launched

Terminations (discontinued projects between 1 July and 30 September 2014)¹

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD1208	Safety / efficacy	haematological malignancies
NME	AZD8848 [#]	Safety / efficacy	asthma
LCM	<i>Iressa</i> IMPRESS	Safety / efficacy	treatment beyond progression

Partnered product.

1 *tremelimumab+Iressa* removed from table Q3 2014. Project is not terminated but is an investigator-sponsored study and, therefore, does not meet the requirement for inclusion in this table.