
GlaxoSmithKline

Product development pipeline 2013

February 2013

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Compound	Type	Indication	Phase	Achieved regulatory review milestones	
				MAA	NDA/BLA
Biopharmaceuticals					
1995057	tumour necrosis factor receptor-1 (TNFR1) domain antibody	acute lung injury	I		
2374697	glucagon like peptide-1 (GLP 1) agonist with half-life improving domain antibody	obesity	I		
2661380 [†]	immunomodulator	solid tumours	I		
3052230 [†]	fibroblast growth factor ligand trap	cancer	I		
otelixizumab	CD3 monoclonal antibody (s.c. & i.v.)	rheumatoid arthritis	I		
249320	myelin-associated glycoprotein monoclonal antibody	stroke	II		
2586881 [†]	recombinant human angiotensin converting enzyme 2	acute lung injury	II		
933776	beta amyloid monoclonal antibody	geographic retinal atrophy	II		
1070806	IL18 monoclonal antibody	type 2 diabetes	II		
belimumab	B lymphocyte stimulator monoclonal antibody (i.v.)	idiopathic membranous nephropathy	II		
belimumab	B lymphocyte stimulator monoclonal antibody (i.v.)	myaesthesia gravis	II		
mapatumumab	tumor necrosis factor–related apoptosis-inducing ligand receptor 1 (TRAIL-R1) monoclonal antibody	advanced hepatocellular carcinoma	II		
mepolizumab	IL5 monoclonal antibody	nasal polyposis	II		
ofatumumab [†]	CD20 human monoclonal antibody (s.c.)	multiple sclerosis	II		
ozanezumab (1223249)	neurite outgrowth inhibitor (NOGO-A) monoclonal antibody	amyotrophic lateral sclerosis	II		
<i>Arzerra</i> (ofatumumab) [†]	CD20 human monoclonal antibody	chronic lymphocytic leukaemia, first line therapy & use in relapsed patients	III		
<i>Arzerra</i> (ofatumumab) [†]	CD20 human monoclonal antibody	diffuse large B cell lymphoma (relapsed patients)	III		
<i>Arzerra</i> (ofatumumab) [†]	CD20 human monoclonal antibody	follicular lymphoma (refractory & relapsed patients)	III		
<i>Benlysta</i> (belimumab)	B lymphocyte stimulator monoclonal antibody (s.c.)	systemic lupus erythematosus	III		
<i>Benlysta</i> (belimumab)	B lymphocyte stimulator monoclonal antibody (i.v.)	vasculitis	III		
mepolizumab	IL5 monoclonal antibody	severe asthma	III		
sirukumab [†]	IL6 human monoclonal antibody (s.c.)	rheumatoid arthritis	III		
albiglutide	GLP 1 agonist	type 2 diabetes	Submitted		S: Jan13
raxibacumab	protective antigen inhibitor	inhalation anthrax	Approved		A: Dec12
Cardiovascular & Metabolic					
1614235 [†] + 2330672	sodium dependent glucose transport (SGLT1) inhibitor + ileal bile acid transport (IBAT) inhibitor	type 2 diabetes	I		
2849466	selective androgen receptor modulator	heart failure	I		
2890457	endogenous gut peptide stimulator	obesity	I		
1278863	prolyl hydroxylase inhibitor	anaemia associated with chronic renal disease	II		
camicinal (962040)	motilin receptor agonist	delayed gastric emptying	II		
losmapimod	p38 kinase inhibitor	acute coronary syndrome (also COPD)	II		
retosiban	oxytocin antagonist	threatened pre-term labour	II		
ronacaleret [†]	calcium receptor antagonist	allogeneic haematopoietic stem cell mobilisation	II		
darapladib	Lp-PLA2 inhibitor	atherosclerosis (also diabetic macular oedema)	III		
Immuno-inflammation					
2245840	SIRT1 activator	psoriasis	II		
2586184 [†]	Janus kinase 1 (JAK1) inhibitor	systemic lupus erythematosus & psoriasis	II		
2941266 [†]	CCR1 chemokine receptor antagonist	rheumatoid arthritis	II		
vercirnon (1605786) [†]	CCR9 chemokine receptor antagonist	Crohn's disease	III		
Infectious Diseases					
2140944	type 2 topoisomerase inhibitor	bacterial infections	I		
2696266 [†]	cephalosporin	bacterial infections	I		
1322322	polypeptide deformylase inhibitor	bacterial infections	II		
2336805 [†]	hepatitis C virus inhibitor	hepatitis C	II		
tafenoquine [†]	8-aminoquinoline	Plasmodium vivax malaria	II		
<i>Relenza</i> i.v. (zanamivir) [†]	neuraminidase inhibitor (i.v.)	influenza	III		
Neurosciences					
356278	phosphodiesterase 4 inhibitor	Huntington's disease	I		
2647544	Lp-PLA2 inhibitor	Alzheimer's disease	I		
239512	H3 receptor antagonist	multiple sclerosis	II		
742457	5HT6 antagonist	dementia	II		
firategrast [†]	dual alpha 4 integrin antagonist (VLA4)	multiple sclerosis	II		
rilapladib	Lp-PLA2 inhibitor	Alzheimer's disease	II		
<i>Patrome</i> (IPX066) [†]	dopamine precursor + DOPA decarboxylase inhibitor	Parkinson's disease	III		N/A
Oncology					
525762	bromodomain inhibitor	NUT gene midline carcinoma	I		
2110183	AKT protein kinase inhibitor	multiple myeloma	I		
2256098	focal adhesion kinase inhibitor	cancer	I		
2636771	phosphatidylinositol 3-kinase (PI3K) inhibitor	cancer	I		
trametinib [†] + 2141795	MEK1/2 inhibitor + AKT protein kinase inhibitor	cancer	I		
2110183	AKT protein kinase inhibitor	Langerhan cell histiocytosis	II		
2110183	AKT protein kinase inhibitor	ovarian cancer	II		
dabrafenib	BRAF protein kinase inhibitor	non-small cell lung cancer	II		
foretinib [†]	mesenchymal-epithelial transition factor (C-met) kinase inhibitor	cancer	II		
<i>Revolade/Promacta</i> (eltrombopag) [†]	thrombopoietin receptor agonist	acute myeloid leukaemia	II		
<i>Revolade/Promacta</i> (eltrombopag) [†]	thrombopoietin receptor agonist	aplastic anaemia	II		
<i>Revolade/Promacta</i> (eltrombopag) [†]	thrombopoietin receptor agonist	myelodysplastic syndromes	II		
trametinib [†]	MEK1/2 inhibitor	KRAS mutant non-small cell lung cancer, second line therapy	II		
trametinib [†] + dabrafenib	MEK1/2 inhibitor + BRAF protein kinase inhibitor	colorectal cancer	II		
trametinib [†] + dabrafenib	MEK1/2 inhibitor + BRAF protein kinase inhibitor	metastatic melanoma, adjuvant therapy	III		
<i>Tyverb/Tykerb</i> (lapatinib)	human epidermal growth factor receptor-2 (Her2) and epidermal growth factor receptor (EGFR) dual kinase inhibitor	breast cancer, adjuvant therapy	III		
<i>Tyverb/Tykerb</i> (lapatinib)	Her2 and EGFR dual kinase inhibitor	gastric cancer	III		
<i>Tyverb/Tykerb</i> (lapatinib)	Her2 and EGFR dual kinase inhibitor	head & neck squamous cell carcinoma (resectable disease)	III		
<i>Votrient</i> (pazopanib)	multi-kinase angiogenesis inhibitor	ovarian cancer, maintenance therapy	III		
<i>Votrient</i> (pazopanib)	multi-kinase angiogenesis inhibitor	renal cell cancer, adjuvant therapy	III		
dabrafenib	BRAF protein kinase inhibitor	metastatic melanoma	Submitted	S: Jul12	S: Jul12
trametinib [†]	MEK1/2 inhibitor	metastatic melanoma	Submitted	S: Feb13	S: Aug12
trametinib [†] + dabrafenib	MEK1/2 inhibitor + BRAF protein kinase inhibitor	metastatic melanoma	Submitted	S: Feb13	
<i>Tyverb/Tykerb</i> (lapatinib)	Her2 and EGFR dual kinase inhibitor	metastatic breast cancer, in combination with trastuzumab	Submitted	S: Feb12	
<i>Votrient</i> (pazopanib)	multi-kinase angiogenesis inhibitor	sarcoma	Approved	A: Aug12	A: Apr12
<i>Revolade/Promacta</i> (eltrombopag) [†]	thrombopoietin receptor agonist	hepatitis C induced thrombocytopenia	Approved	S: May12	A: Nov12
Ophthalmology					
darapladib	Lp-PLA2 inhibitor	diabetic macular oedema (also atherosclerosis)	II		
Respiratory					
1325756	CXCR2 chemokine receptor antagonist	COPD	I		
2256294	soluble epoxide hydrolase inhibitor	COPD	I		
2269557	phosphoinositide 3 kinase inhibitor	asthma & COPD	I		
2339345	sodium channel blocker	cough	I		
fluticasone furoate (685698)	glucocorticoid agonist + long-acting beta2 agonist	COPD	I		
+ vilanterol [†] + umeclidinium (573719)	+ muscarinic acetylcholine antagonist		I		
961081 [†]	muscarinic antagonist, beta2 agonist	COPD	II		
2190915 [†]	5-lipoxygenase-activating protein (FLAP) inhibitor	asthma	II		
2245035	toll-like receptor 7 agonist	asthma	II		
dilmapiomod	p38 kinase inhibitor (i.v.)	acute lung injury & acute respiratory distress syndrome	II		
fluticasone furoate (685698)	glucocorticoid agonist + muscarinic acetylcholine antagonist	asthma	II		
+ umeclidinium (573719)			II		
losmapimod	p38 kinase inhibitor (oral)	COPD (also acute coronary syndrome)	II		
fluticasone furoate (685698)	glucocorticoid agonist	asthma	III		
<i>Relvar/Breo</i> (vilanterol [†] + fluticasone furoate)	long-acting beta2 agonist + glucocorticoid agonist	COPD – mortality outcomes	III		
umeclidinium (573719)	muscarinic acetylcholine antagonist	COPD	III		
vilanterol [†]	long-acting beta2 agonist	COPD	III		
<i>Relvar/Breo</i> (vilanterol [†] + fluticasone furoate)	long-acting beta2 agonist + glucocorticoid agonist	asthma	Submitted	S: Jun12	
<i>Relvar/Breo</i> (vilanterol [†] + fluticasone furoate)	long-acting beta2 agonist + glucocorticoid agonist	COPD	Submitted	S: Jun12	S: Jul12
<i>Anoro</i> (umeclidinium + vilanterol [†])	muscarinic acetylcholine antagonist + long-acting beta2 agonist	COPD	Submitted	S: Jan13	S: Dec12
Paediatric Vaccines					
<i>S. pneumoniae</i> paediatric next generation [†]	recombinant – conjugated	Streptococcus pneumoniae disease prophylaxis	II		
MMR	live attenuated	measles, mumps, rubella prophylaxis	III (US)	A: Nov97	
<i>Mosquirix</i> (Malaria RTS,S) [†]	recombinant	malaria prophylaxis (Plasmodium falciparum)	III		N/A
<i>MenHibrix</i> (Hib-MenCY-TT)	conjugated	Neisseria meningitis groups C & Y & Haemophilus influenzae type b disease prophylaxis	Approved	N/A	A: Jun12
<i>Nimenrix</i> (MenACWY-TT)	conjugated	Neisseria meningitis groups A, C, W & Y disease prophylaxis	Approved	A: Apr12	
Other Vaccines					
HIV [†]	recombinant	HIV disease prophylaxis	I		
NTHi [†]	recombinant	non-typeable Haemophilus influenzae prophylaxis	I		
Staphylococcus Aureus	recombinant – conjugated	Staphylococcus aureus prophylaxis	I		
HIV [†]	recombinant	HIV disease immunotherapy	II		
Tuberculosis [†]	recombinant	tuberculosis prophylaxis	II		
Zoster [†]	recombinant	Herpes Zoster prophylaxis	III		
Flu (pre-) pandemic	H5N1 inactivated split – monovalent (Quebec)	pre-pandemic & pandemic influenza prophylaxis	Submitted	N/A	S: Feb12
Flu vaccine	inactivated split – quadrivalent	seasonal influenza prophylaxis	Approved	S: Mar12	A: Dec12
Antigen-Specific Cancer Immunotherapeutic					
PRAME immunotherapeutic [†]	recombinant	treatment of resectable non-small cell lung cancer	I		
WT1 immunotherapeutic	recombinant	treatment of breast cancer	I		
MAGE-A3 immunotherapeutic [†]	recombinant	treatment of bladder cancer	II		
MAGE-A3 immunotherapeutic [†]	recombinant	treatment of melanoma	III		
MAGE-A3 immunotherapeutic [†]	recombinant	treatment of non-small cell lung cancer	III		
Rare Diseases					
migalastat HCl [†] + ERT	pharmacological chaperone + enzyme replacement therapy (ERT)	Fabry disease	II		
drisapersen (2402968) [†]	antisense oligonucleotide	Duchenne muscular dystrophy	III		
2696273 [†]	ex-vivo stem cell gene therapy	adenosine deaminase severe combined immune deficiency (ADA-SCID)	III		
migalastat HCl [†]	pharmacological chaperone	Fabry disease	III		
Stiefel (late-stage assets only)					
2894512 [†]	non-steroidal anti-inflammatory	atopic dermatitis	II		
alitretinoin [†]	retinoic acid receptor modulator	chronic hand eczema	III	N/A	
<i>Duac</i> low dose	clindamycin/benzoyl peroxide gel	acne vulgaris	Submitted	S: Nov11	S: Nov10
<i>Fabior</i> (tazarotene foam)	retinoid foam	acne vulgaris	Approved	N/A	A: May12
<i>Sorilux</i>	vitamin D3 analog	scalp psoriasis	Approved	N/A	A: Sep12
HIV (ViiV Healthcare)					
1265744	HIV integrase inhibitor (long-acting parenteral formulation)	HIV infections	II		
dolutegravir + abacavir sulphate + lamivudine	HIV integrase inhibitor + reverse transcriptase inhibitors (fixed dose combination)	HIV infections	III		
dolutegravir	HIV integrase inhibitor	HIV infections	Submitted	S: Dec12	S: Dec12
Key					
[†]	In-license or other alliance relationship with third party	MAA	Marketing Authorisation Application (Europe)	Phase II	Determination of dose and initial evaluation of efficacy, conducted in a small number of patients
S	Month of first submission	NDA	New Drug Application (USA)		
A	Month of first regulatory approval (for MAA, this is the first EU approval letter)	Phase I	Evaluation of clinical pharmacology, usually conducted in volunteers	Phase III	Large comparative study (compound versus placebo and/or established treatment) in patients to establish clinical benefit and safety
BLA	Biological License Application				

MAA and NDA/BLA regulatory review milestones shown in the table below are those that have been achieved. Future filing dates are not included in this list.

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Option-based alliances with third parties that include assets in Phase I or later development:

Company	Disease Area	Phase
Cancer Research UK	cancer	I
ChemoCentryx	inflammatory disease	II*
Dynavax Technologies	cutaneous & systemic lupus erythematosus	II
ISIS Pharmaceuticals	transthyretin-mediated amyloidosis	II/III
OncoMed Pharmaceuticals	oncology	I**
Prosensa Therapeutics	neuroscience	II
Ranbaxy Laboratories	respiratory	II
Telethon Institute for Gene Therapy	stem cell gene therapy	II**
Affiris	Alzheimer's disease treatment vaccine	II

* CCX168

** Two assets

This document outlines GlaxoSmithKline's drug development portfolio. The content of the drug development portfolio will change over time as new compounds progress from discovery to development and from development to the market. Owing to the nature of the drug development process, many of these compounds, especially those in early stages of investigation, may be terminated as they progress through development. For competitive reasons, new projects in pre-clinical development have not been disclosed and some project types may not have been identified.

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this document, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk factors' in the 'Financial review & risk' section in the company's Annual Report 2012.



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