GSK Product development pipeline

March 2015

Pipeline, products and competition

Pharmaceuticals and Vaccines product development pipeline

Key

†	In-licence or other alliance relationship with third party
*	Also being developed for indications in another therapeutic area
S	Month of first submission
A	Month of first regulatory approval (for MAA, this is the first EU approval letter)
BLA	Biological Licence Application
MAA	Marketing Authorisation Application (Europe)
NDA	New Drug Application (USA)

Phase I	Evaluation of clinical pharmacology, usually conducted in volunteers
Phase II	Determination of dose and initial evaluation of efficacy, conducted in a small number of patients
Phase III	Large comparative study (compound versus placebo and/or established treatment) in patients to establish clinical benefit and safety

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.

				Achieved regulatory review milestones	
Compound	Type	Indication	Phase	MAA	NDA/BLA
Respiratory					
2126458	phosphoinositide 3 kinase (PI3K) inhibitor	idiopathic pulmonary fibrosis	I		
2256294	soluble epoxide hydrolase (sEH) inhibitor	chronic obstructive pulmonary disease (COPD)	I		
2862277	tumour necrosis factor receptor-1 (TNFR1) domain antibody	acute lung injury	I		
961081† + fluticasone furoate	muscarinic acetylcholine antagonist, beta2 agonist (MABA) + glucocorticoid agonist	COPD	I		
961081†	MABA	COPD	II		
2245035	toll-like receptor 7 agonist	asthma	II		
2269557	PI3K inhibitor	asthma & COPD	II		
2586881†	recombinant human angiotensin converting enzyme 2	acute lung injury	II		
danirixin	CXCR2 chemokine receptor antagonist	COPD	II		
fluticasone furoate + umeclidinium	glucocorticoid agonist + muscarinic acetylcholine antagonist	asthma COPD overlap syndrome	II		
losmapimod	p38 kinase inhibitor (oral)	COPD*	II		
mepolizumab	IL5 monoclonal antibody	nasal polyposis*	II		
fluticasone furoate + vilanterol† + umeclidinium	glucocorticoid agonist + long-acting beta2 agonist + muscarinic acetylcholine antagonist	COPD	III		
mepolizumab	IL5 monoclonal antibody	COPD*	III		
Relvar/Breo Ellipta (vilanterol† + fluticasone furoate)	long-acting beta2 agonist + glucocorticoid agonist	COPD – mortality outcomes	III		
vilanterol†	long-acting beta2 agonist	COPD	III		
mepolizumab	IL5 monoclonal antibody	severe eosinophilic asthma*	Submitted	S: Nov14	S: Nov14
Anoro Ellipta (umeclidinium + vilanterol†)	muscarinic acetylcholine antagonist + long-acting beta2 agonist	COPD	Approved	A: May14	A: Dec13
Arnuity Ellipta (fluticasone furoate)	glucocorticoid agonist	asthma	Approved	N/A	A: Aug14
Incruse Ellipta (umeclidinium)	muscarinic acetylcholine antagonist	COPD*	Approved	A: Apr14	A:Apr14
Relvar/Breo Ellipta (vilanterol† + fluticasone furoate)	long-acting beta2 agonist + glucocorticoid agonist	asthma	Approved	A: Nov13	S: Jun14
Paediatric Vaccines					
RSV	recombinant	respiratory syncytial virus prophylaxis (maternal immunisation)	I		
RSV	recombinant viral vector	respiratory syncytial virus prophylaxis	I		
S. pneumoniae next generation†	recombinant – conjugated	Streptococcus pneumoniae disease prophylaxis	II		
MMR	live attenuated	measles, mumps, rubella prophylaxis	III (US)	N/A	
Mosquirix (Malaria RTS,S)†	recombinant	malaria prophylaxis (Plasmodium falciparum)	Submitted	S: Jun14	N/A
DTPa-HBV-IPV/Hib†	conjugated	diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, haemophilus influenza	Approved II (US)	N/A	
Nimenrix (MenACWY-TT)	conjugated	Neisseria meningitis groups A, C, W & Y disease prophylaxis	Approved II (US)	A: Apr12	

Pipeline, products and competition
continued

Pharmaceuticals and Vaccines product development pipeline continued

Compound	Type	Indication	Phase	Achieved regulatory review milestones MAA	NDA/BLA
Other Vaccines					
Malaria next generation†	recombinant	malaria prophylaxis (Plasmodium falciparum)	II		
NTHi†	recombinant	non-typeable Haemophilus influenzae prophylaxis	II		
Tuberculosis†	recombinant	tuberculosis prophylaxis	II		
Hepatitis C	recombinant viral vector	hepatitis C virus prophylaxis	II		
Ebola†	recombinant viral vector	prevention of filovirus haemorrhagic fevers caused by Ebola Zaire virus	III		
Zoster†	recombinant	Herpes Zoster prophylaxis	III		
Antigen-Specific Cancer Immunotherapeutic					
MAGE-A3 immunotherapeutic†	recombinant	treatment of melanoma	III		
HIV (ViiV Healthcare)					
cabotegravir (1265744)	HIV integrase inhibitor (long-acting parenteral formulation)	HIV infections	II		
cabotegravir (1265744)	HIV integrase inhibitor (long-acting parenteral formulation)	HIV pre-exposure prophylaxis	II		
Triumeq (dolutegravir + abacavir sulphate + lamivudine)	HIV integrase inhibitor + reverse transcriptase inhibitors (fixed dose combination)	HIV infections – fixed dose combination	Approved	A: Sep14	A: Aug14
Oncology					
525762	bromodomain inhibitor	cancer	I		
2256098	focal adhesion kinase inhibitor	cancer	I		
2636771	PI3K inhibitor	cancer	I		
2816126	enhancer of zeste homologue2 (EZH2) inhibitor	cancer	I		
2849330	ErbB3 monoclonal antibody	cancer	I		
2857916	beta cell maturation antigen antibody drug conjugate	multiple myeloma	I		
2879552	lysine-specific demethylase 1 (LSD1) inhibitor	cancer	I		
3052230†	fibroblast growth factor ligand trap	cancer	I		
afuresertib (2110183)	AKT protein kinase inhibitor	multiple myeloma	I		
Votrient (pazopanib) + MK-3475†	multi-kinase angiogenesis inhibitor + PD-1 monoclonal antibody	renal cell cancer	I		
afuresertib (2110183)	AKT protein kinase inhibitor	ovarian cancer	II		
Mekinist (trametinib)† + Tafinlar (dabrafenib)	MEK1/2 inhibitor + BRAF protein kinase inhibitor	non-small cell lung cancer	II		
Mekinist (trametinib)† + Tafinlar (dabrafenib)	MEK1/2 inhibitor + BRAF protein kinase inhibitor	rare cancers	II		
Mekinist (trametinib)† + *Tafinlar* (dabrafenib) + panitumumab†	MEK1/2 inhibitor + BRAF protein kinase inhibitor + human anti-EGFR monoclonal antibody	colorectal cancer	II		
Revolade/*Promacta* (eltrombopag)†	thrombopoietin receptor agonist	acute myeloid leukaemia	II		
Arzerra (ofatumumab)†	CD20 human monoclonal antibody	chronic lymphocytic leukaemia, use in relapsed patients	III		
Arzerra (ofatumumab)†	CD20 human monoclonal antibody	follicular lymphoma (refractory & relapsed patients)	III		
Mekinist (trametinib)† + Tafinlar (dabrafenib)	MEK1/2 inhibitor + BRAF protein kinase inhibitor	metastatic melanoma, adjuvant therapy	III		
Revolade/*Promacta* (eltrombopag)†	thrombopoietin receptor agonist	myelodysplastic syndromes	III		
Votrient (pazopanib)	multi-kinase angiogenesis inhibitor	renal cell cancer, adjuvant therapy	III		
Arzerra (ofatumumab)†	CD20 human monoclonal antibody	chronic lymphocytic leukaemia, first line therapy	Approved	A: Jun14	A: Apr14
Mekinist (trametinib)†	MEK1/2 inhibitor	metastatic melanoma	Approved	A: Jul14	A: May13
Mekinist (trametinib)† + *Tafinlar* (dabrafenib)	MEK1/2 inhibitor + BRAF protein kinase inhibitor	metastatic melanoma	Approved		A: Jan 14
Revolade/*Promacta* (eltrombopag)†	thrombopoietin receptor agonist	aplastic anaemia	Approved	S: Nov14	A: Aug14

Pharmaceuticals and Vaccines product development pipeline continued

Compound	Type	Indication	Phase	Achieved regulatory review milestones	
				MAA	NDA/BLA
Cardiovascular & Metabolic					
1278863	prolyl hydroxylase inhibitor (topical)	wound healing	I		
2798745	transient receptor potential cation channel V4 (TRPV4) antagonist	heart failure	I		
2881078	selective androgen receptor modulator	muscle wasting	I		
1278863	prolyl hydroxylase inhibitor	anaemia associated with chronic renal disease	II		
2330672	ileal bile acid transport inhibitor	type 2 diabetes & cholestatic pruritus	II		
camicinal	motilin receptor agonist	delayed gastric emptying	II		
Eperzan/Tanzeum (albiglutide)	GLP 1 agonist	type 1 diabetes	II		
losmapimod	p38 kinase inhibitor	focal segmental glomerular sclerosis*	II		
otelixizumab	CD3 monoclonal antibody	new onset type 1 diabetes	II		
losmapimod	p38 kinase inhibitor	acute coronary syndrome*	III		
retosiban	oxytocin antagonist	threatened pre-term labour	III		
Eperzan/Tanzeum (albiglutide)	GLP 1 agonist	type 2 diabetes	Approved	A: Mar14	A:Apr14
Immuno-inflammation					
2618960	IL7 receptor monoclonal antibody	autoimmune disease	I		
2646264	spleen tyrosine kinase (Syk) inhibitor (topical)	chronic urticaria	I		
2831781†	LAG3 monoclonal antibody	autoimmune disease	I		
2982772	RIP1 kinase inhibitor	autoimmune disease	I		
3050002†	CCL20 monoclonal antibody	autoimmune disease	I		
3117391†	macrophage targeted histone deacetylase inhibitor	rheumatoid arthritis	I		
3196165 (MOR103)†	granulocyte macrophage colony-stimulating factor monoclonal antibody	rheumatoid arthritis	II		
Benlysta (belimumab)	B lymphocyte stimulator monoclonal antibody (i.v.)	transplant rejection*	II		
Benlysta (belimumab)	B lymphocyte stimulator monoclonal antibody (s.c.)	systemic lupus erythematosus*	III		
Benlysta (belimumab)	B lymphocyte stimulator monoclonal antibody (i.v.)	vasculitis*	III		
sirukumab†	IL6 human monoclonal antibody (s.c.)	rheumatoid arthritis	III		
Rare Diseases					
2398852† + 23156898†	SAP monoclonal antibody + SAP depleter (CPHPC)	amyloidosis	I		
2696274†	ex-vivo stem cell gene therapy	metachromatic leukodystrophy	II		
2696275†	ex-vivo stem cell gene therapy	Wiscott-Aldrich syndrome	II		
ozanezumab	neurite outgrowth inhibitor (NOGO-A) monoclonal antibody	amyotrophic lateral sclerosis	II		
2696273†	ex-vivo stem cell gene therapy	adenosine deaminase severe combined immune deficiency (ADA-SCID)	III		
mepolizumab	IL5 monoclonal antibody (s.c.)	eosinophilic granulomatosis with polyangiitis*	III		
Volibris (ambrisentan)†	endothelin A antagonist	chronic thromboembolic pulmonary hypertension	III		
Infectious Diseases					
2838232	antiviral maturation inhibitor	HIV infections	I		
2878175	NS5B polymerase inhibitor	hepatitis C	I		
2140944	type 2 topoisomerase inhibitor	bacterial infections	II		
tafenoquine†	8-aminoquinoline	Plasmodium vivax malaria	III		
Relenza i.v. (zanamivir)†	neuraminidase inhibitor (i.v.)	influenza	III		
Neurosciences					
ofatumumab†	CD20 human monoclonal antibody (s.c.)	neuromyelitis optica*	II		
Benlysta (belimumab)	B lymphocyte stimulator monoclonal antibody (i.v.)	myaesthenia gravis*	II		
ofatumumab†	CD20 human monoclonal antibody (s.c.)	multiple sclerosis*	II		
rilapladib	Lp-PLA2 inhibitor	Alzheimer's disease	II		

Pipeline, products and competition
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Pharmaceuticals and Vaccines product development pipeline continued

Compound	Type	Indication	Phase	Achieved regulatory review milestones	
				MAA	NDA/BLA
Ophthalmology					
933776	beta amyloid monoclonal antibody	geographic retinal atrophy	II		
Dermatology					
1940029	stearoyl CoA desaturase 1 inhibitor (topical)	acne vulgaris	I		
umeclidinium	muscarinic acetylcholine antagonist (topical)	hyperhidrosis*	I		
2894512†	non-steroidal anti-inflammatory	atopic dermatitis & psoriasis	II		
chlorhexidine	cationic polybiguanide (topical)	umbilical cord care	III		
ofatumumab†	CD20 human monoclonal antibody (s.c.)	pemphigus vulgaris*	III		
Toctino (alitretinoin)†	retinoic acid receptor modulator	chronic hand eczema	III	N/A	

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Option-based alliances with third parties that include assets in phase I and phase III development:

Company	Disease Area	Phase
Adaptimmune	cancer	I
Cancer Research UK	cancer	I
ISIS Pharmaceuticals	hepatitis B	I
	transthyretin-mediated amyloidosis	III
OncoMed Pharmaceuticals	oncology	I
	oncology	II
Shionogi	bacterial infection	I

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
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 Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2014.

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