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# GSK Product development pipeline

November 2015

# Pharmaceuticals and Vaccines product development pipeline

Compound	Type	Indication	Phase	Achieved regulatory review milestones	
				MAA	NDA/BLA
<b>HIV<sup>^</sup> and Infectious Diseases</b>					
dolutegravir + rilpivirine <sup>†</sup>	HIV integrase inhibitor + non-nucleoside reverse transcriptase inhibitor	HIV infections - two drug maintenance regimen	III		
tafenoquine <sup>†</sup>	8-aminoquinoline	Plasmodium vivax malaria	III		
Relenza i.v. <sup>†</sup>	neuraminidase inhibitor (i.v.)	influenza	III		
cabotegravir	HIV integrase inhibitor (long-acting parenteral formulation)	HIV infections	II		
cabotegravir	HIV integrase inhibitor (long-acting parenteral formulation)	HIV pre-exposure prophylaxis	II		
gepolidacin (2140944)	type 2 topoisomerase inhibitor	bacterial infections	II		
danirixin	chemokine (C-X-C Motif) receptor 2 (CXCR2) antagonist	influenza*	II		
3228836 <sup>1</sup>	antisense oligonucleotide	hepatitis B	I		
2878175	nonstructural protein 5B (NS5B) polymerase inhibitor	hepatitis C	I		
2838232	antiviral maturation inhibitor	HIV infections	I		
<b>Respiratory</b>					
Nucala (mepolizumab)	interleukin 5 (IL5) monoclonal antibody	severe eosinophilic asthma*	Submitted	S: Nov14	S: Nov14
fluticasone furoate + vilanterol <sup>†</sup> + umeclidinium	glucocorticoid agonist + long-acting beta2 agonist + muscarinic acetylcholine antagonist	chronic obstructive pulmonary disease (COPD)	III		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	COPD*	III		
vilanterol <sup>†</sup>	long-acting beta2 agonist	COPD	III		
961081 <sup>†</sup>	muscarinic acetylcholine antagonist, beta2 agonist (MABA)	COPD	II		
2245035	toll-like receptor 7 (TLR7) agonist	asthma	II		
2269557	phosphatidylinositol 3-kinase delta (PI3Kδ) inhibitor	asthma and COPD	II		
2586881 <sup>†</sup>	recombinant human angiotensin converting enzyme 2	acute lung injury	II		
2862277	tumour necrosis factor receptor-1 (TNFR1) domain antibody	acute lung injury	II		
danirixin	chemokine (C-X-C Motif) receptor 2 (CXCR2) antagonist	COPD*	II		
fluticasone furoate + umeclidinium	glucocorticoid agonist + muscarinic acetylcholine antagonist	asthma COPD overlap syndrome	II		
losmapimod	p38 kinase inhibitor (oral)	COPD*	II		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	nasal polyposis*	II		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	hypereosinophilic syndrome (HES)*	II		
2256294	soluble epoxide hydrolase (sEH) inhibitor	COPD	I		
961081 <sup>†</sup> + fluticasone furoate	muscarinic acetylcholine antagonist, beta2 agonist (MABA) + glucocorticoid agonist	COPD	I		

# Pharmaceuticals and Vaccines product development pipeline

*continued*

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				MAA	NDA/BLA
<b>Oncology</b>					
3377794 <sup>2</sup>	NY-ESO-1 autologous engineered TCR-T cells (engineered TCR)	sarcoma, multiple myeloma, non-small cell lung cancer, melanoma and ovarian cancer	II		
tarextumab <sup>3</sup>	notch 2/3 monoclonal antibody	pancreatic and small cell lung cancer	II		
brontictuzumab <sup>3</sup>	notch 1 monoclonal antibody	solid tumours and haematological malignancies	I		
3174998 <sup>†</sup>	OX40 agonist monoclonal antibody	solid tumours and haematological malignancies	I		
3052230 <sup>†</sup>	fibroblast growth factor (FGF) ligand trap	mesothelioma and non-small cell lung cancer	I		
2879552	lysine-specific demethylase 1 (LSD1) inhibitor	acute myeloid leukemia and small cell lung cancer	I		
2857916 <sup>†</sup>	beta cell maturation antigen antibody drug conjugate	multiple myeloma	I		
2849330	erb-b2 receptor tyrosine kinase 3 (ErbB3) monoclonal antibody	solid tumours	I		
2816126	enhancer of zeste homologue2 (EZH2) inhibitor	solid tumours and haematological malignancies	I		
2636771	phosphatidylinositol 3-kinase (PI3K) beta inhibitor	castration resistant prostate cancer	I		
2256098	focal adhesion kinase inhibitor	mesothelioma	I		
525762	BET family bromodomain inhibitor	solid tumours and haematological malignancies	I		
<b>Immuno-inflammation</b>					
sirukumab <sup>†</sup>	interleukin 6 (IL6) human monoclonal antibody (s.c.)	rheumatoid arthritis	III		
sirukumab <sup>†</sup>	interleukin 6 (IL6) human monoclonal antibody (s.c.)	giant cell arteritis	III		
<i>Benlysta</i>	B lymphocyte stimulator monoclonal antibody (s.c.)	systemic lupus erythematosus*	III		
<i>Benlysta</i>	B lymphocyte stimulator monoclonal antibody (i.v.)	vasculitis*	III		
<i>Benlysta</i>	B lymphocyte stimulator monoclonal antibody (i.v.)	transplant rejection*	II		
3196165 <sup>†</sup>	granulocyte macrophage colony-stimulating factor monoclonal antibody	rheumatoid arthritis	II		
2330811	oncostatin M (OSM) monoclonal antibody	systemic sclerosis	I		
2618960	interleukin 7 (IL7) receptor monoclonal antibody	Sjogren's syndrome	I		
2646264	spleen tyrosine kinase (Syk) inhibitor (topical)	chronic urticaria	I		
2831781 <sup>†</sup>	lymphocyte activation gene 3 (LAG3) protein monoclonal antibody	autoimmune diseases	I		
2982772	receptor-interacting protein 1 (RIP1) kinase inhibitor	psoriasis, rheumatoid arthritis and ulcerative colitis	I		
3050002 <sup>†</sup>	chemokine (C-C motif) ligand 20 (CCL20) monoclonal antibody	psoriatic arthritis	I		
3117391 <sup>†</sup>	macrophage targeted histone deacetylase inhibitor	rheumatoid arthritis	I		
<b>Rare Diseases</b>					
2696273 <sup>†</sup>	ex-vivo stem cell gene therapy	adenosine deaminase severe combined immune deficiency (ADA-SCID)	Submitted	S: May15	
2998728 <sup>†</sup>	transthyretin (TTR) production inhibitor	transthyretin-mediated amyloidosis	III		

# Pharmaceuticals and Vaccines product development pipeline

## continued

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				MAA	NDA/BLA
<b>Rare Diseases</b> <i>continued</i>					
mepolizumab	interleukin 5 (IL5) monoclonal antibody	eosinophilic granulomatosis with polyangiitis*	III		
2398852 <sup>†</sup> + 2315698 <sup>†</sup>	serum amyloid P component (SAP) monoclonal antibody + SAP depleter (CPHPC)	amyloidosis	II		
2696274 <sup>†</sup>	ex-vivo stem cell gene therapy	metachromatic leukodystrophy	II		
2696275 <sup>†</sup>	ex-vivo stem cell gene therapy	Wiscott-Aldrich syndrome	II		
2696277 <sup>†</sup>	ex-vivo stem cell gene therapy	beta-thalassemia	I		
<b>Vaccines</b>					
<i>Shingrix</i> <sup>†</sup> (Zoster vaccine)	recombinant	Herpes Zoster prophylaxis	III		
MMR	live attenuated	measles, mumps, rubella prophylaxis	III (US)	N/A	
Ebola <sup>†</sup>	recombinant viral vector	Ebola haemorrhagic fever prophylaxis	III		
Group B Streptococcus	conjugated	Group B streptococcus prophylaxis (maternal immunisation)	II		
<i>S. pneumoniae</i> next generation <sup>†</sup>	recombinant – conjugated	Streptococcus pneumoniae disease prophylaxis	II		
COPD <sup>†</sup>	recombinant	non-typeable Haemophilus influenzae and Moraxella catarrhalis prophylaxis	II		
Hepatitis C <sup>†</sup>	recombinant viral vector	hepatitis C virus prophylaxis	II		
Malaria next generation <sup>†</sup>	recombinant	malaria prophylaxis (Plasmodium falciparum)	II		
Men ABCWY	recombinant – conjugated	Meningococcal A,B,C,W and Y disease prophylaxis	II		
Pseudomonas <sup>5</sup>	recombinant	pseudomonas infection prophylaxis	II		
Shigella <sup>†</sup>	conjugated and outer membrane	Shigella diarrhea prophylaxis	II		
Tuberculosis <sup>†</sup>	recombinant	tuberculosis prophylaxis	II		
RSV	recombinant	respiratory syncytial virus prophylaxis (maternal immunisation)	II		
RSV	replication-defective recombinant viral vector	respiratory syncytial virus prophylaxis	I		
HIV <sup>†</sup>	recombinant proteins	HIV infection prophylaxis	I		
<b>Other Pharmaceuticals</b>					
<b>Metabolic</b>					
retosiban	oxytocin antagonist	threatened pre-term labour	III		
daprodustat (1278863) <sup>#</sup>	prolyl hydroxylase inhibitor	anaemia associated with chronic renal disease	II		
2330672	ileal bile acid transport (IBAT) inhibitor	cholestatic pruritus	II		
camicinal	motilin receptor agonist	delayed gastric emptying	II		
<i>Eperzan/Tanzeum</i> (albiglutide)	glucagon-like peptide 1 (GLP1) receptor agonist	type 1 diabetes	II		
losmapimod	p38 kinase inhibitor	focal segmental glomerular sclerosis*	II		
otelixizumab	cluster of differentiation 3 (CD3) monoclonal antibody	new onset type 1 diabetes	II		
daprodustat (1278863) <sup>#</sup>	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		
oxytocin (inhaled) <sup>†</sup>	oxytocin	postpartum hemorrhage	I		

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## *continued*

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				MAA	NDA/BLA
<b>Dermatology</b>					
chlorhexidine	cationic polybiguanide (topical)	umbilical cord care	Submitted	S: Oct15	
<i>Toctino</i> (alitretinoin) <sup>†</sup>	retinoic acid receptor modulator	chronic hand eczema	III	N/A	
2894512 <sup>†</sup>	non-steroidal anti-inflammatory	atopic dermatitis and psoriasis	II		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	severe atopic dermatitis*	I		
umeclidinium	muscarinic acetylcholine antagonist (topical)	hyperhidrosis*	I		
<b>Neurosciences</b>					
933776	beta amyloid monoclonal antibody	geographic retinal atrophy / Alzheimer's disease	II		
<i>Benlysta</i>	B lymphocyte stimulator monoclonal antibody (i.v.)	myasthenia gravis*	II		
rilapladib	lipoprotein-associated phospholipase A2 (Lp-PLA2) inhibitor	Alzheimer's disease	II		

### KEY:

<sup>†</sup> In-license or other alliance relationship with third party

<sup>^</sup> ViiV Healthcare, a global specialist HIV company with GSK, Pfizer, Inc. and Shionogi Limited as shareholders, is responsible for developing and delivering HIV medicines.

\* Also being developed for indications in another therapeutic area

<sup>1</sup> Option-based alliance with Isis Pharmaceuticals

<sup>2</sup> Option-based alliance with Adaptimmune Ltd.

<sup>3</sup> Option-based alliance with OncoMed Pharmaceuticals

<sup>4</sup> Option-based alliance with Telethon and Ospedale San Raffaele

<sup>5</sup> Option-based alliance with Valveva

# USAN name, INN approval pending

S Month of first submission

A Month of first regulatory approval (for MAA, this is the first EU approval letter)

BLA Biological License 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

Pending completion of the proposed divestment of GSK's rights in ofatumumab for autoimmune indications, announced 21 August 2015, ofatumumab's development programmes have been removed from this listing.

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

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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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