

The background features several overlapping, rounded, organic shapes in a gradient of orange and yellow. The largest shape is a central, bright orange circle that overlaps with other shapes in lighter and darker tones of the same color palette.

GSK Product development pipeline

March 2016

Pharmaceuticals and Vaccines product development pipeline

Key

†	In-licence or other alliance relationship with third party	S	Month of first submission
^	ViiV Healthcare, a global specialist HIV company with GSK, Pfizer, Inc. and Shionogi Limited as shareholders, is responsible for developing and delivering HIV medicines.	BLA	Biological Licence Application
*	Also being developed for indications in another therapeutic area	MAA	Marketing Authorisation Application (Europe)
1	Option-based alliance with Ionis Pharmaceuticals	NDA	New Drug Application (US)
2	Option-based alliance with Adaptimmune Ltd.	Phase I	Evaluation of clinical pharmacology, usually conducted in volunteers
3	Option-based alliance with OncoMed Pharmaceuticals	Phase II	Determination of dose and initial evaluation of efficacy, conducted in a small number of patients
4	Option-based alliance with Telethon and Ospedale San Raffaele	Phase III	Large comparative study (compound versus placebo and/or established treatment) in patients to establish clinical benefit and safety
5	Option-based alliance with Valneva		

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.

Compound	Type	Indication	Phase	Achieved regulatory review milestones	
				MAA	NDA/BLA
HIV[^] and Infectious Diseases					
dolutegravir + rilpivirine [†]	HIV integrase inhibitor + non-nucleoside reverse transcriptase inhibitor (NNRTI)	HIV infections – two drug maintenance regimen	III		
3684934	HIV attachment inhibitor	HIV infections	III		
tafenoquine [†]	8-aminoquinoline	Plasmodium vivax malaria	III		
Relenza i.v. [†]	neuraminidase inhibitor (i.v.)	influenza	III		
cabotegravir	HIV integrase inhibitor (long-acting parenteral formulation)	HIV pre-exposure prophylaxis	II		
cabotegravir + rilpivirine [†]	HIV integrase inhibitor + non-nucleoside reverse transcriptase inhibitor (NNRTI) (long-acting parenteral formulations)	HIV infections	II		
gepotidacin (2140944)	type 2 topoisomerase inhibitor	bacterial infections	II		
danirixin	chemokine (C-X-C Motif) receptor 2 (CXCR2) antagonist	influenza*	II		
3532795	HIV maturation inhibitor	HIV infections	II		
2838232	HIV maturation inhibitor	HIV infections	I		
3228836 ¹	HBV antisense oligonucleotide	hepatitis B	I		
3389404 ¹	HBV LICA antisense oligonucleotide	hepatitis B	I		
2878175	nonstructural protein 5B (NS5B) polymerase inhibitor	hepatitis C	I		
Respiratory					
fluticasone furoate + vilanterol [†] + umeclidinium	glucocorticoid agonist + long-acting beta2 agonist + muscarinic acetylcholine antagonist	chronic obstructive pulmonary disease (COPD)	III		
mepolizumab 961081 [†]	interleukin 5 (IL5) monoclonal antibody	COPD*	III		
961081 [†]	muscarinic acetylcholine antagonist, beta2 agonist (MABA)	COPD	II		
961081 [†]	muscarinic acetylcholine antagonist, beta2 agonist (MABA) + glucocorticoid agonist	COPD	II		
2245035	toll-like receptor 7 (TLR7) agonist	asthma	II		
2269557	phosphatidylinositol 3-kinase delta (PI3Kδ) inhibitor	asthma and COPD	II		
2586881 [†]	recombinant human angiotensin converting enzyme 2 (rhACE2)	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 + vilanterol [†] + umeclidinium	glucocorticoid agonist + long-acting beta2 agonist + muscarinic acetylcholine antagonist	asthma	II		
losmapimod	p38 kinase inhibitor	COPD*	II		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	nasal polyposis*	II		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	hypereosinophilic syndrome*	II		
sirukumab [†]	interleukin 6 (IL6) human monoclonal antibody	severe asthma*	II		
3008348	alpha V beta 6 integrin antagonist	idiopathic pulmonary fibrosis	I		

Pharmaceuticals and Vaccines product development pipeline

continued

Compound	Type	Indication	Phase	Achieved regulatory review milestones	
				MAA	NDA/BLA
Oncology					
3377794 ²	NY-ESO-1 autologous engineered TCR-T cells (engineered TCR)	sarcoma, multiple myeloma, non-small cell lung cancer, melanoma and ovarian cancer	II		
tarextumab ³	notch 2/3 monoclonal antibody	small cell lung cancer	II		
brontictuzumab ³	notch 1 monoclonal antibody	solid tumours and haematological malignancies	I		
3174998 [†]	OX40 agonist monoclonal antibody	solid tumours and haematological malignancies	I		
2879552	lysine-specific demethylase 1 (LSD1) inhibitor	acute myeloid leukemia and small cell lung cancer	I		
2857916 [†]	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		
Immuno-inflammation					
sirukumab [†]	interleukin 6 (IL6) human monoclonal antibody	rheumatoid arthritis*	III		
sirukumab [†]	interleukin 6 (IL6) human monoclonal antibody	giant cell arteritis*	III		
Benlysta	B lymphocyte stimulator monoclonal antibody (s.c.)	systemic lupus erythematosus*	III		
Benlysta	B lymphocyte stimulator monoclonal antibody (i.v.)	vasculitis*	III		
Benlysta	B lymphocyte stimulator monoclonal antibody (i.v.)	transplant rejection*	II		
Benlysta + Rituxan [†]	B lymphocyte stimulator monoclonal antibody (s.c.) + cluster of differentiation 20 (CD20) monoclonal antibody (i.v.)	Sjogren's syndrome	II		
3196165 [†]	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 [†]	lymphocyte activation gene 3 (LAG3) protein monoclonal antibody	autoimmune disease	I		
2982772	receptor-interacting protein 1 (RIP1) kinase inhibitor	psoriasis, rheumatoid arthritis and ulcerative colitis	I		
3050002 [†]	chemokine (C-C motif) ligand 20 (CCL20) monoclonal antibody	psoriatic arthritis	I		
3117391 [†]	macrophage targeted histone deacetylase inhibitor	rheumatoid arthritis	I		
3179106	rearranged during transfection (RET) kinase inhibitor	inflammatory disorders of the bowel	I		
Rare diseases					
2696273 [†]	ex-vivo stem cell gene therapy	adenosine deaminase severe combined immune deficiency (ADA-SCID)	Submitted	S: May15	
2998728 [†]	transthyretin (TTR) production inhibitor	transthyretin-mediated amyloidosis	III		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	eosinophilic granulomatosis with polyangiitis*	III		
2398852 [†] + 2315698 [†]	serum amyloid P component (SAP) monoclonal antibody + SAP depleter (CPHPC)	amyloidosis	II		
2696274 [†]	ex-vivo stem cell gene therapy	metachromatic leukodystrophy	II		
2696275 [†]	ex-vivo stem cell gene therapy	Wiscott-Aldrich syndrome	II		
2696277 [†]	ex-vivo stem cell gene therapy	beta-thalassemia	I		

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continued

Compound	Type	Indication	Phase	Achieved regulatory review milestones	
				MAA	NDA/BLA
Vaccines					
<i>Shingrix</i> [†] (Zoster Vaccine)	recombinant	Herpes Zoster prophylaxis	III		
MMR	live attenuated	measles, mumps, rubella prophylaxis	III (US)	N/A	
Ebola [†]	recombinant viral vector	Ebola haemorrhagic fever prophylaxis	II		
Group B Streptococcus	conjugated	Group B streptococcus prophylaxis (maternal immunisation)	II		
S. pneumoniae next generation [†]	recombinant – conjugated	Streptococcus pneumoniae disease prophylaxis	II		
COPD [†]	recombinant	reduction of the frequency of COPD exacerbations associated with non-typeable Haemophilus influenzae and Moraxella catarrhalis	II		
Hepatitis C [†]	recombinant viral vector	hepatitis C virus prophylaxis	II		
Malaria next generation [†]	recombinant	malaria prophylaxis (Plasmodium falciparum)	II		
Men ABCWY	recombinant – conjugated	meningococcal A,B,C,W and Y disease prophylaxis in adolescents	II		
Pseudomonas ⁵	recombinant	pseudomonas infection prophylaxis	II		
Shigella [†]	conjugated and outer membrane	Shigella diarrhea prophylaxis	II		
Tuberculosis [†]	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 [†]	recombinant proteins	HIV infection prophylaxis	I		
Other pharmaceuticals					
Metabolic					
retosiban	oxytocin antagonist	spontaneous pre-term labour	III		
daprodustat (1278863)	prolyl hydroxylase inhibitor	anaemia associated with chronic renal disease	II		
2330672	ileal bile acid transport (IBAT) inhibitor	cholestatic pruritus	II		
camicalin	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)	new onset type 1 diabetes	II		
daprodustat (1278863)	prolyl hydroxylase inhibitor (topical) monoclonal antibody	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) [†]	oxytocin	postpartum hemorrhage	I		
Dermatology					
chlorhexidine	cationic polybiguanide (topical)	prevention of omphalitis	Submitted	S: Oct15	
2894512 [†]	non-steroidal anti-inflammatory (topical)	atopic dermatitis	II		
2894512 [†]	non-steroidal anti-inflammatory (topical)	psoriasis	II		
2981278	ROR gamma inverse agonist (topical)	psoriasis	II		
umeclidinium	muscarinic acetylcholine antagonist (topical)	hyperhidrosis*	II		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	severe atopic dermatitis*	I		
Neurosciences					
933776	beta amyloid monoclonal antibody	geographic retinal atrophy	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		
n/a	ocular target LICA antisense oligonucleotide [†]	geographic atrophy age-related macular disease	I		