

Pipeline, products and competition

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 Valveva		

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		
dolutegravir + lamivudine	HIV integrase inhibitor + nucleoside reverse transcriptase inhibitor (NRTI)	HIV infections	III		
3684934	HIV attachment inhibitor	HIV infections	III		
cabotegravir	HIV integrase inhibitor (long-acting parenteral formulation)	HIV pre-exposure prophylaxis	III		
cabotegravir + rilpivirine [†]	HIV integrase inhibitor + non-nucleoside reverse transcriptase inhibitor (NNRTI) (long-acting parenteral formulations)	HIV infections	III		
tafenoquine [†]	8-aminoquinoline	plasmodium vivax malaria	III		
Relenza i.v. [†]	neuraminidase inhibitor (i.v.)	influenza	III		
gepoticadin (2140944)	type 2 topoisomerase inhibitor	bacterial infections	II		
danirixin i.v.	chemokine (C-X-C Motif) receptor 2 (CXCR2) antagonist	influenza*	II		
2878175+RG101 [†]	nonstructural protein 5B (NS5B) polymerase inhibitor + anti-miR122 antisense oligonucleotide	hepatitis C	II		
3342830	antibacterial cephalosporin	bacterial infection	I		
2838232	HIV maturation inhibitor	HIV infections	I		
3228836 [†]	HBV antisense oligonucleotide	hepatitis B	I		
3389404 [†]	HBV LICA antisense oligonucleotide	hepatitis B	I		
Respiratory					
fluticasone furoate + vilanterol [†] + umeclidinium	glucocorticoid agonist + long-acting beta2 agonist + muscarinic acetylcholine antagonist	chronic obstructive pulmonary disease (COPD)	Submitted	S: Dec16	S: Nov16
mepolizumab	interleukin 5 (IL5) monoclonal antibody	COPD*	III		
fluticasone furoate + vilanterol [†] + umeclidinium	glucocorticoid agonist + long-acting beta2 agonist + muscarinic acetylcholine antagonist	asthma	III		
961081 [†]	muscarinic acetylcholine antagonist, beta2 agonist (MABA)	COPD	II		
961081 [†] + fluticasone furoate	muscarinic acetylcholine antagonist, beta2 agonist (MABA) + glucocorticoid agonist	COPD	II		
danirixin	chemokine (C-X-C Motif) receptor 2 (CXCR2) antagonist (oral)	COPD*	II		
2269557	phosphatidylinositol 3-kinase delta (PI3Kδ) inhibitor	COPD (acute and chronic)	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		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	hypereosinophilic syndrome*	II		
mepolizumab	interleukin 5 (IL5) monoclonal antibody	nasal polyposis*	II		
2245035	toll-like receptor 7 (TLR7) agonist	asthma	II		
sirukumab [†]	interleukin 6 (IL6) human monoclonal antibody (s.c.)	severe asthma*	II		

Pipeline, products and competition continued

Pharmaceuticals and Vaccines product development pipeline continued

Compound	Type	Indication	Phase	Achieved regulatory review milestones	
				MAA	NDA/BLA
Respiratory continued					
2269557	phosphatidylinositol 3-kinase delta (PI3Kδ) inhibitor	activated PI3K delta syndrome	I		
3772847 [†]	interleukin 33r (IL33r) monoclonal antibody	severe asthma	I		
2586881 [†]	recombinant human angiotensin converting enzyme 2 (rhACE2)	pulmonary arterial hypertension	I		
3008348	alpha V beta 6 integrin antagonist	idiopathic pulmonary fibrosis	I		
2269557	phosphatidylinositol 3-kinase delta (PI3Kδ) inhibitor	bronchiectasis	I		
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		
3174998 [†]	OX40 agonist monoclonal antibody	solid tumours and haematological malignancies	I		
2816126	enhancer of zeste homologue2 (EZH2) inhibitor	solid tumours and haematological malignancies	I		
525762	BET family bromodomain inhibitor	solid tumours and haematological malignancies	I		
2879552	lysine-specific demethylase 1 (LSD1) inhibitor	acute myeloid leukemia and small cell lung cancer	I		
2857916 [†]	B-cell maturation antigen antibody drug conjugate	multiple myeloma	I		
3326595	protein arginine methyltransferase 5 (PRMT5) inhibitor	cancer	I		
3359609	induced T-cell costimulator (ICOS) agonist antibody	cancer	I		
1795091	toll-like receptor 4 (TLR4) agonist	cancer	I		
2636771	phosphatidylinositol 3-kinase (PI3K) beta inhibitor	castration resistant prostate cancer	I		
Immuno-inflammation					
sirukumab [†]	interleukin 6 (IL6) human monoclonal antibody	rheumatoid arthritis*	Submitted	S: Sep16	S: Sep16
Benlysta	B lymphocyte stimulator monoclonal antibody (s.c.)	systemic lupus erythematosus*	Submitted	S: Sep16	S: Sep16
sirukumab [†]	interleukin 6 (IL6) human monoclonal antibody	giant cell arteritis*	III		
3196165 [†]	granulocyte macrophage colony-stimulating factor monoclonal antibody	osteoarthritis	II		
3196165 [†]	granulocyte macrophage colony-stimulating factor monoclonal antibody	rheumatoid arthritis	II		
Benlysta + Rituxan	B lymphocyte stimulator monoclonal antibody (s.c.) + cluster of differentiation 20 (CD20) monoclonal antibody (i.v.)	Sjogren's syndrome	II		
2982772	receptor-interacting protein 1 (RIP1) kinase inhibitor	psoriasis and rheumatoid arthritis	II		
3117391 [†]	macrophage targeted histone deacetylase inhibitor	rheumatoid arthritis	II		
2330811	oncostatin M (OSM) monoclonal antibody	systemic sclerosis	I		
2982772	receptor-interacting protein 1 (RIP1) kinase inhibitor	ulcerative colitis	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		
3050002 [†]	chemokine (C-C motif) ligand 20 (CCL20) monoclonal antibody	psoriatic arthritis	I		
3179106	rearranged during transfection (RET) kinase inhibitor	inflammatory disorders of bowel	I		

Pharmaceuticals and Vaccines product development pipeline continued

Compound	Type	Indication	Phase	Achieved regulatory review milestones	
				MAA	NDA/BLA
Rare diseases					
Strimvelis [†]	ex-vivo stem cell gene therapy	adenosine deaminase severe combined immune deficiency (ADA-SCID)	Approved	A: May16	
2998728 ¹	transthyretin (TTR) production inhibitor	transthyretin-mediated amyloidosis	III		
2696274 [†]	ex-vivo stem cell gene therapy	metachromatic leukodystrophy	III		
2696275 [†]	ex-vivo stem cell gene therapy	Wiscott-Aldrich syndrome	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		
2696277 ⁴	ex-vivo stem cell gene therapy	beta-thalassemia	II		
2256098	focal adhesion kinase inhibitor	pulmonary arterial hypertension (PAH)	I		
Vaccines					
<i>Shingrix</i> [†] (Zoster Vaccine)	recombinant	Herpes Zoster prophylaxis	Submitted	S: Nov16	S: Oct 16
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 moderate and severe acute exacerbations in COPD patients by targeting 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		
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	II		
HIV [†]	recombinant proteins	HIV infection prophylaxis	II		
Other pharmaceuticals					
Metabolic					
retosiban	oxytocin antagonist	spontaneous pre-term labour	III		
daprodustat (1278863)	prolyl hydroxylase inhibitor (oral)	anaemia associated with chronic renal disease	III		
2330672	ileal bile acid transport (IBAT) inhibitor	cholestatic pruritus	II		
2798745	transient receptor potential cation channel V4 (TRPV4) antagonist	heart failure	II		
1070806	interleukin 18 (IL18) neutralisation mAb	delayed graft function after renal transplantation	II		
otelixumab	cluster of differentiation 3 (CD3) monoclonal antibody	new onset type 1 diabetes	II		
daprodustat (1278863)	prolyl hydroxylase inhibitor (topical)	wound healing	I		
3008356	diglyceride acyltransferase (DGAT) 1 inhibitor	nonalcoholic steatohepatitis	I		
2881078	selective androgen receptor modulator	muscle wasting	I		
oxytocin (inhaled) [†]	oxytocin	postpartum hemorrhage	I		
Dermatology					
mepolizumab	interleukin 5 (IL5) monoclonal antibody	atopic dermatitis*	II		
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		
Neurosciences					
IONIS-GSK4-L ¹	ocular target LICA antisense oligonucleotide	geographic atrophy age-related macular disease	I		

Pipeline, products and competition continued

Pharmaceutical products, competition and intellectual property

Products	Compounds	Indication(s)	Major competitor brands	Patent expiry dates ³	
				US	EU
Respiratory					
<i>Anoro Ellipta</i>	umeclidinium bromide/ vilanterol terfenatate	COPD	Spiriva Handihaler/ Respimat, Stiolto/ Spiolto Respimat Ultibro Breezhaler, Duaklir Genuair Bevespi Aerosphere	2025 (NCE) 2027-2030 (device/formulation)	2029 (NCE) 2022-2025 (device/formulation)
<i>Arnuiy Ellipta</i>	fluticasone furoate	asthma	Qvar, Pulmicort Asmanex, Alvesco	2021 (NCE) 2027-2030 (device/formulation)	NA
<i>Avamys/Veramyst</i>	fluticasone furoate	rhinitis	Nasonex	2021 ²	2023
<i>Flixotide/Flovent</i>	fluticasone propionate	asthma/COPD	Qvar, Singulair	expired (Diskus device) 2018-2026 ¹ (HFA-device)	expired (Diskus device) 2017 (HFA-device)
<i>Incruse Ellipta</i>	umeclidinium bromide	COPD	Spiriva Handihaler/ Respimat, Eklira Genuair	2025 (NCE) 2027-2030 (device/formulation)	2029 (NCE) 2022-2025 (device/formulation)
<i>Nucala</i>	mepolizumab	severe eosinophilic asthma	Xolair, Cinqair	expired ⁴	2020 ⁴
<i>Relvar/Breo Ellipta</i>	fluticasone furoate/ vilanterol terfenatate	asthma/COPD	Symbicort, Foster, Flutiform, Dulera	2022 (NCE) 2027-2030 (device/formulation)	2027 (NCE) 2022-2025 (device/formulation)
<i>Seretide/Advair*</i>	salmeterol xinafoate/ fluticasone propionate	asthma/COPD	Symbicort, Foster, Flutiform, Dulera	expired (Diskus device) 2018-2026 ¹ (HFA-device)	expired (Diskus device) 2017 ⁵ (HFA-device)
<i>Serevent</i>	salmeterol xinafoate	asthma/COPD	Foradil, Spiriva, Handihaler/Respimat Onbrez	expired (Diskus device)	expired (Diskus device) 2019 (HFA-device)
<i>Ventolin HFA</i>	albuterol sulphate	asthma/COPD	generic companies	2018-2026 ¹ (HFA-device)	2017 (HFA-device)
Anti-virals					
<i>Valtrex</i>	valaciclovir	genital herpes, coldsores, shingles	Famvir	expired	expired
<i>Zeffix/Epivir-HBV</i>	lamivudine	chronic hepatitis B	Hepsera	expired	expired
Central nervous system					
<i>Lamictal</i>	lamotrigine	epilepsy, bipolar disorder	Keppra, Dilantin	expired	expired
<i>Imigran/Imitrex</i>	sumatriptan	migraine	Zomig, Maxalt, Relpax	expired	expired
<i>Seroxat/Paxil</i>	paroxetine	depression, various anxiety disorders	Effexor, Cymbalta, Lexapro	expired	expired
Cardiovascular and urogenital					
<i>Eperzan/Tanzeum</i>	albiglutide	Type 2 diabetes	Victoza, Byetta Bydureon, Lyxumia Trulicity	2022	2027
<i>Avodart</i>	dutasteride	benign prostatic hyperplasia	Proscar, Flomax, finasteride	expired	2017
<i>Coreg CR</i>	carvedilol phosphate	mild-to-severe heart failure, hypertension, left ventricular dysfunction post MI	Toprol XL	2026 ^{1,2} (formulation)	NA

* See 'Principal risks and uncertainties' on page 254 for details of uncertainty on the timing of follow-on competition.

1 See Note 46 to the financial statements, 'Legal proceedings'.

2 Generic competition possible in 2017.

3 Includes Supplementary Protection Certificates which were granted in multiple countries in EU and patent term extensions granted in the US.

4 Data exclusivity expires 2025 (EU) and 2027 (US).

5 Generic competition exists in some markets.

Pharmaceutical products, competition and intellectual property continued

Products	Compounds	Indication(s)	Major competitor brands	Patent expiry dates ³	
				US	EU
Anti-bacterials					
<i>Augmentin</i>	amoxicillin/clavulanate potassium	common bacterial infections	generic products	NA	expired
Rare diseases					
<i>Volibris</i>	ambrisentan	pulmonary hypertension	Tracleer, Revatio	NA	2020
Immuno-inflammation					
<i>Benlysta</i>	belimumab	systemic lupus erythematosus		2023	2026
HIV					
<i>Epzicom/Kivexa</i>	lamivudine and abacavir	HIV/AIDS	Truvada, Atripla, Descovy, Genvoya, Odefsey	expired	2019 ^{1,2} (combination)
<i>Lexiva/Telzir</i>	fosamprenavir	HIV/AIDS	Prezista, Kaletra, Reyataz	2018 ¹	2019
<i>Selzentry/Celsentri</i>	maraviroc	HIV/AIDS	Isentress, Intelence, Prezista	2021	2022
<i>Tivicay</i>	dolutegravir	HIV/AIDS	Isentress, Prezista, Reyataz, Kaletra	2027	2029
<i>Triumeq</i>	dolutegravir, lamivudine and abacavir	HIV/AIDS	Truvada, Atripla, Descovy, Genvoya, Odefsey	2027	2029
<i>Trizivir</i>	lamivudine, zidovudine and abacavir	HIV/AIDS	Truvada, Atripla, Descovy, Genvoya, Odefsey	expired	expired

Vaccines products, competition and intellectual property

Products	Compounds	Indication(s)	Major competitor brands	Patent expiry dates ³	
				US	EU
<i>Bexsero</i>	meningococcal group-B vaccine	Meningitis group B prevention	<i>Trumenba</i>	2027	2028 ¹
<i>Boostrix</i>	diphtheria, tetanus, acellular pertussis	diphtheria, tetanus, acellular Pertussis booster vaccination	Adacel	2017	2017
<i>Infanrix Hexa/Pediarix</i>	diphtheria, tetanus, pertussis, polio, hepatitis B, Haemophilus influenzae type B (EU)	Prophylaxis against diphtheria, tetanus, pertussis, polio, hepatitis B, Haemophilus influenzae type B (EU)	Pentacel, Pediacel, Pentaxim, Pentavac, Hexaxim, Hexyon Vaxelis	2018	expired
<i>Cervarix</i>	HPV 16 & 18 virus like particles (VLPs), AS04 adjuvant (MPL + aluminium hydroxide)	human papilloma virus type 16 and 18	Gardasil (Silgard)	2020	2020
<i>Fluarix Tetra</i>	split inactivated influenza antigens (2 virus subtypes A and 2 subtype B)	seasonal influenza prophylaxis	Intenza, Flumist QIV, Vaxigrip QIV, Fluzone QIV, Fluzone High Dose	2022	2022
<i>FluLaval</i>	split inactivated influenza antigens (2 virus subtypes A and 2 subtype B)	seasonal influenza prophylaxis	Vaxigrip, Mutagrip, Fluzone, Influvac, Aggripal, Fluad, Intenza, Flumist	2022	2022
<i>Menveo</i>	meningococcal group A, C, W-135 and Y conjugate vaccine	Meningitis group A, C, W-135 and Y prophylaxis	Mencevax, Menactra	2025	2025
<i>Prepandrix</i>	derived split inactivated influenza virus antigen, AS03 adjuvant	pandemic H5N1 influenza prophylaxis	Aflunov, Vepacel	–	2026
<i>Priorix², Priorix Tetra^{ab}, Varilrix^b</i>	live attenuated measles, mumps, rubella and varicella vaccine	measles, mumps, rubella and chickenpox prophylaxis	MMR II (M-M-RVaxPro), Proquad, Varivax	2019 ⁴	expired
<i>Rotarix</i>	Human rotavirus RIX4414 strain	Rotavirus prophylaxis	Rotateq	–	2020
<i>Synflorix</i>	conjugated pneumococcal polysaccharide	Prophylaxis against invasive disease, pneumonia, acute otitis media	Prevenar (Prevnar)	NA	2024

1 See Note 46 to the financial statements, 'Legal proceedings'.

2 Generic competition commenced in many markets during 2016.

3 Includes Supplementary Protection Certificates which were granted in multiple countries in EU and patent term extensions granted in the US.

4 Refers to *Priorix* and *Priorix Tetra*, as all patents on *Varilrix* have expired.

a Related compounds/indications are measles, mumps and rubella vaccine/prophylaxis

b Related compound is varicella vaccine

Pipeline, products and competition continued

Consumer Healthcare products and competition				
Brand	Products	Application	Markets	Competition
Wellness				
<i>Panadol</i> and <i>Panadol Cold & Flu</i>	tablets, caplets, infant syrup drops	paracetamol-based treatment for headache, joint pain, fever, cold symptoms	global (except US)	Advil, Pfizer Aspirin, Bayer Tylenol, Johnson & Johnson
<i>Voltaren</i>	topical gel	non-steroidal, diclofenac based anti-inflammatory	global	Advil, Pfizer Aspirin, Bayer Tylenol, Johnson & Johnson
<i>Otrivin</i>	nasal spray	nasal decongestant	Germany, Poland, Russia, Sweden, Ukraine	Afrin, Merck Nasivin, Merck
<i>Theraflu</i>	tablets and syrups	cold and flu relief	Russia, Poland, Ukraine, US	Tylenol Cold & Flu, Johnson & Johnson Mucinex, Reckitt Benckiser Lemsip, Reckitt Benckiser
<i>Flonase</i>	nasal spray	allergy relief	US	Claritin, Bayer, Nasacort, Sanofi
<i>Flixonase, Piriton</i>	nasal spray, tablets	allergy relief	UK, Ireland	Benadryl, Johnson & Johnson
<i>ENO</i>	effervescent	immediate relief antacid	global (except US)	Estomazil, Hypermarca Gelusil, Pfizer
<i>Tums</i>	chewable tablets	immediate relief antacid	US	Alka-Seltzer, Bayer Gaviscon, Reckitt Benckiser Rolaids, Sanofi
<i>Nicorette</i> (US), <i>NicoDerm</i> , <i>Nicotinell</i> (ex. Australia)	lozenges, gum and trans-dermal patches	treatment of nicotine withdrawal as an aid to smoking reduction and cessation	global	Nicorette, Johnson & Johnson NiQuitin, Perrigo
Oral health				
<i>Sensodyne</i> , <i>Pronamel</i>	toothpastes, toothbrushes, mouth rinse	relief of dentinal hypersensitivity. Pronamel additionally protects against acid erosion	global	Colgate Sensitive Pro-Relief, Colgate-Palmolive Elmex, Colgate-Palmolive Oral B, Procter & Gamble
<i>Parodontax</i> / <i>Corsodyl</i>	toothpaste, medicated mouthwash, gel and spray	helps prevent bleeding gums, treats and prevents gingivitis	Germany, Ireland Italy, United Kingdom	Colgate Total Gum Health, Colgate-Palmolive Yunnan Baiyao, State Enterprise (China)
<i>Polident</i> , <i>Poligrip</i> , <i>Corega</i>	denture adhesive, denture cleanser	improve retention and comfort of dentures, cleans dentures	global	Fixodent and Kukident, Procter & Gamble, Steradent, Reckitt Benckiser
<i>Aquafresh</i>	toothpastes, toothbrushes mouthwashes	aids prevention of dental cavities, maintains healthy teeth, gums and fresh breath	global	Colgate, Colgate-Palmolive Crest, Procter & Gamble Oral-B, Procter & Gamble
Skin health				
<i>Zovirax</i> <i>Abreva</i>	topical cream and non-medicated patch	lip care to treat and prevent the onset of cold sores	global	Compeed, Johnson & Johnson Carmex, Carma Labs Blistex, Blistex Incorporated retail own label
Nutrition				
<i>Horlicks</i>	malted drinks and foods	nutritional beverages & food	Indian sub-continent, United Kingdom, Ireland	Bournvita, Mondelez Complan, Heinz