

February

2007

Product Development Pipeline

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Therapeutic area	Compound	Type	Indication	Phase	Estimated submission dates			
					MAA	NDA		
Cardiovascular & Metabolic	256073	high affinity nicotinic acid receptor (HM74A) agonist	dyslipidaemia	I				
	568859 [†]	lipoprotein-associated phospholipase A2 (Lp-PLA2) inhibitor	atherosclerosis	I				
	813893	factor Xa inhibitor	prevention of stroke in atrial fibrillation	I				
	856553	p38 kinase inhibitor	atherosclerosis (also rheumatoid arthritis & chronic obstructive pulmonary disease, COPD)	I				
	rilapladib [†]	Lp-PLA2 inhibitor	atherosclerosis	I				
	501516 [†]	peroxisome proliferator-activator receptor (PPAR) delta agonist	dyslipidaemia	II				
	681323	p38 kinase inhibitor	atherosclerosis (also COPD, neuropathic pain & rheumatoid arthritis)	II				
	darapladib [†]	Lp-PLA2 inhibitor	atherosclerosis	II/III				
	ambrisentan [†]	endothelin A antagonist	pulmonary arterial hypertension	III	2007	N/A		
	Coreg CR [†] + ACE inhibitor	beta blocker + angiotensin converting enzyme inhibitor	hypertension – fixed dose combination	III	N/A			
	Arixtra	synthetic factor Xa inhibitor	treatment of acute coronary syndrome	Approvable	S:Jul06	AL:Feb07		
	Coreg CR [†]	beta blocker	hypertension & congestive heart failure – once-daily	Approved	N/A	A:Oct06		
	Metabolic projects							
	189075 [†]	sodium dependent glucose transport (SGLT2) inhibitor	obesity	I				
	376501	PPAR gamma partial agonist	type 2 diabetes	I				
	625019	PPAR pan agonist	type 2 diabetes & metabolic syndrome	I				
	189075 [†]	SGLT2 inhibitor	type 2 diabetes	II				
	677954	PPAR pan agonist	type 2 diabetes, metabolic syndrome & dyslipidaemia	II				
	869682 [†]	SGLT2 inhibitor	obesity	II				
	albiglutide (716155) [†]	glucagon-like peptide 1 agonist	type 2 diabetes	II				
	Avandia	PPAR gamma agonist	atherosclerosis in type 2 diabetes	II				
	Avandamet XR	PPAR gamma agonist + metformin	type 2 diabetes – extended release	III	N/A	2007		
	Avandia	PPAR gamma agonist	prevention of diabetes	III	N/A	2007		
Avandia	PPAR gamma agonist	prevention of disease progression	III	N/A	2007			
Avandia + simvastatin	PPAR gamma agonist + statin	type 2 diabetes	III	N/A	2007			
Avandaryl/Avaglim [†]	PPAR gamma agonist + sulphonylurea	type 2 diabetes – fixed dose combination	Approved	A:Jun06	A:Dec05			
Infectious Diseases	565154	oral pleuromutilin	treatment of bacterial infections	I				
	742510	oral pleuromutilin	treatment of bacterial infections	I				
	tafenoquine [†]	8-aminoquinoline	<i>Plasmodium vivax</i> malaria	II				
	farglitazar	PPAR gamma agonist	hepatic fibrosis	II				
	sitamaquine	8-aminoquinoline	treatment of visceral leishmaniasis	II		N/A		
	chlorproguanil, dapsone + artesunate (CDA) [†]	antifolate + artemisinin	treatment of uncomplicated malaria	III	2008	N/A		
	Altanax/Altargo	topical pleuromutilin	bacterial skin infections	Approvable	S:Jun06	AL:Dec06		
	Antivirals							
	625433	polymerase inhibitor	hepatitis C	I				
	825780 [†]	DNA antiviral vaccine	HIV infection	I				
	364735 [†]	integrase inhibitor	HIV infection	II				
	Relenza [†]	neuraminidase inhibitor	influenza prophylaxis	Approved	A:Aug06	A:Mar06		
	Musculoskeletal, Inflammation, Gastrointestinal & Urology	221149	oxytocin antagonist	threatened pre-term labour	I			
		232802	3G-selective oestrogen receptor modulator	treatment of menopausal symptoms	I			
		267268	vitronectin integrin antagonist	age-related macular degeneration	I			
		315234	monoclonal antibody	rheumatoid arthritis	I			
		366074 [†]	potassium channel opener	overactive bladder	I			
		751689 [†]	calcium antagonist	osteoporosis	I			
		768974 [†]	parathyroid hormone agonist	osteoporosis	I			
		relacatib [†]	cathepsin K inhibitor	osteoporosis & osteoarthritis (also bone metastases)	I			
		274150	selective iNOS inhibitor	rheumatoid arthritis (also migraine)	II			
		681323	p38 kinase inhibitor (oral)	rheumatoid arthritis (also atherosclerosis, COPD & neuropathic pain)	II			
		856553	p38 kinase inhibitor (oral)	rheumatoid arthritis (also atherosclerosis & COPD)	II			
876008 [†]		corticotrophin releasing factor (CRF1) antagonist	irritable bowel syndrome (also depression & anxiety)	II				
casopitant		NK1 antagonist	overactive bladder (also depression & anxiety, chemotherapy induced & postoperative nausea & vomiting)	II				
dutasteride + testosterone		5-alpha reductase inhibitor + testosterone	hypogonadism – fixed dose combination	II				
HuMax-CD20 (ofatumumab) [†]		human monoclonal antibody	rheumatoid arthritis (also chronic lymphocytic leukaemia and non-Hodgkin's lymphoma)	II				
mepolizumab		anti-IL5 monoclonal antibody	eosinophilic esophagitis (also severe asthma & nasal polyposis)	II				
rosiglitazone XR		PPAR gamma agonist	rheumatoid arthritis (also Alzheimer's disease)	II				
solabegron		beta3 adrenergic agonist	irritable bowel syndrome	II				
solabegron		beta3 adrenergic agonist	overactive bladder	II				
Avodart + alpha blocker		5-alpha reductase inhibitor + alpha blocker	benign prostatic hyperplasia – fixed dose combination	III				
Avodart		5-alpha reductase inhibitor	reduction in the risk of prostate cancer	III				
belimumab [†]		anti-B lymphocyte stimulator monoclonal antibody	systemic lupus erythematosus	III				
Entereg/Entrareg [†]		peripheral mu-opioid antagonist	opioid induced bowel dysfunction	III				
mepolizumab		anti-IL5 monoclonal antibody	hypereosinophilic syndrome (also severe asthma & nasal polyposis)	III				
Entereg/Entrareg [†]		peripheral mu-opioid antagonist	post operative ileus	Approvable		AL:Jul05 & Nov06		
Boniva/Bonviva [†]		bisphosphonate	treatment of postmenopausal osteoporosis – i.v. injection	Approved	A:Mar06	A:Jan06		
Neurosciences		163090	5HT1 antagonist	depression & anxiety	I			
		189254	histamine H3 antagonist	dementia	I			
		239512	histamine H3 antagonist	dementia	I			
		561679 [†]	CRF1 antagonist	depression & anxiety	I			
		588045	5HT1 antagonist	depression & anxiety	I			
		598809	dopamine D3 antagonist	drug dependency	I			
		729327	AMPA receptor modulator	schizophrenia	I			
	823296	NK1 antagonist	depression & anxiety	I				
	274150	selective iNOS inhibitor	migraine (also rheumatoid arthritis)	II				
	372475 [†]	triple (5HT/noradrenaline/dopamine) re-uptake inhibitor	depression	II				
	468816	glycine antagonist	smoking cessation	II				
	649868 [†]	orexin antagonist	sleep disorders	II				
	681323	p38 kinase inhibitor	neuropathic pain (also atherosclerosis, COPD & rheumatoid arthritis)	II				
	683699 [†]	dual alpha4 integrin antagonist (VLA4)	multiple sclerosis	II				
	742457	5HT6 antagonist	dementia	II				
	773812	mixed 5HT/dopaminergic antagonist	schizophrenia	II				
	842166	non-cannabinoid CB2 agonist	inflammatory pain	II				
	876008 [†]	CRF1 antagonist	depression & anxiety (also irritable bowel syndrome)	II				
	casopitant	NK1 antagonist	depression & anxiety (also overactive bladder, chemotherapy induced & postoperative nausea & vomiting)	II				
	talnetant	NK3 antagonist	schizophrenia	II				
	gepirone ER [†]	5HT1a agonist	major depressive disorder, once-daily	III		2007		
	Lamictal XR	sodium channel inhibitor	epilepsy – partial generalised tonic-clonic seizures, once-daily	III	N/A	2007		
	rosiglitazone XR	PPAR gamma agonist	Alzheimer's disease (also rheumatoid arthritis)	III				
	Lamictal XR	sodium channel inhibitor	epilepsy – partial seizures, once-daily	Submitted	N/A	S:Nov06		
	Requip extended release	non-ergot dopamine agonist	restless legs syndrome	Submitted	N/A	S:Oct06		
	Requip Modutab/XL 24 hour [†]	non-ergot dopamine agonist	Parkinson's disease – once-daily controlled release formulation	Submitted	S:Dec05	S:Feb07		
	Trexima [†]	5HT1 agonist + naproxen	migraine – fixed dose combination	Approvable	N/A	AL:Jun06		
	Wellbutrin XL [†]	noradrenaline/dopamine re-uptake inhibitor	seasonal affective disorder	Approved	N/A	A:Jun06		
	Wellbutrin XL/IXR [†]	noradrenaline/dopamine re-uptake inhibitor	depression	Approved	A:Dec06	A:Aug03		
	Oncology	559448 [†]	thrombopoietin agonist	thrombocytopenia	I			
		626616 [†]	human kinase inhibitor	chemoprotection	I			
		pazopanib	vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor	non-small cell lung cancer & colorectal cancer (in combination with other treatment regimens)	I			
		relacatib [†]	cathepsin K inhibitor	bone metastases (also osteoporosis & osteoarthritis)	I			
		pazopanib + Tykerb	VEGF tyrosine kinase inhibitor + ErbB-2 and epidermal growth factor receptor (EGFR) dual kinase inhibitor	breast cancer	II			
		pazopanib + Tykerb	VEGF tyrosine kinase inhibitor + ErbB-2 and EGFR dual kinase inhibitor	other cancers	II			
		Promacta (eltrombopag) [†]	thrombopoietin agonist	chemotherapy induced thrombocytopenia	II			
		Promacta (eltrombopag) [†]	thrombopoietin agonist	hepatitis C	II			
		casopitant	NK1 antagonist	chemotherapy induced & postoperative* nausea & vomiting (*US only) (also overactive bladder, depression & anxiety)	III			
		HuMax-CD20 (ofatumumab) [†]	human monoclonal antibody	chronic lymphocytic leukaemia & non-Hodgkin's lymphoma (also rheumatoid arthritis)	III			
		Hycamtin	topo-isomerase I inhibitor	ovarian cancer, first-line therapy	III			
Hycamtin		topo-isomerase I inhibitor	small cell lung cancer, second-line therapy – oral formulation	III	2007	2007		
pazopanib		VEGF tyrosine kinase inhibitor	renal cell cancer	III				
Promacta (eltrombopag) [†]		thrombopoietin agonist	long-term idiopathic thrombocytopenic purpura	III				
Promacta (eltrombopag) [†]		thrombopoietin agonist	short-term idiopathic thrombocytopenic purpura	III		2007/08		
Tykerb		ErbB-2 and EGFR dual kinase inhibitor	breast cancer, adjuvant therapy	III				
Tykerb		ErbB-2 and EGFR dual kinase inhibitor	breast cancer, first-line therapy	III				
Tykerb		ErbB-2 and EGFR dual kinase inhibitor	head & neck squamous cell carcinomas	III				
Tykerb		ErbB-2 and EGFR dual kinase inhibitor	refractory breast cancer	Submitted	S:Oct06	S:Sep06		
Arranonil/Atriance		guanidine arabinoside prodrug	acute lymphoblastic leukaemia & lymphomas	Approved	S:May06	A:Oct05		
Hycamtin		topo-isomerase I inhibitor	cervical cancer, second-line therapy	Approved	A:Nov06	A:Jun06		
Respiratory		256066	PDE IV inhibitor (inhaled)	COPD	I			
		573719	muscarinic acetylcholine antagonist	COPD	I			
	679586	monoclonal antibody	severe asthma	I				
	961081 [†]	muscarinic antagonist, beta2 agonist	COPD	I				
	159797 [†]	long-acting beta2 agonist	COPD, also COPD & asthma in combination with a glucocorticoid agonist	II				
	159802 [†]	long-acting beta2 agonist	COPD, also COPD & asthma in combination with a glucocorticoid agonist	II				
	233705	muscarinic acetylcholine antagonist	COPD	II				
	256066	PDE IV inhibitor (inhaled)	asthma	II				
	256066	PDE IV inhibitor (intranasal)	allergic rhinitis	II				
	597901 [†]	long-acting beta2 agonist	COPD, also COPD & asthma in combination with a glucocorticoid agonist	II				
	642444 [†]	long-acting beta2 agonist	COPD, also COPD & asthma in combination with a glucocorticoid agonist	II				
	678007 [†]	long-acting beta2 agonist	COPD, also COPD & asthma in combination with a glucocorticoid agonist	II				
	681323	p38 kinase inhibitor (oral)	COPD (also atherosclerosis, neuropathic pain & rheumatoid arthritis)	II				
	685698	glucocorticoid agonist	asthma & COPD in combination with a long-acting beta2 agonist (also as Avamys/Allermist for allergic rhinitis)	II				
	784568	glucocorticoid agonist (intranasal)	allergic rhinitis	II				
	799943	glucocorticoid agonist	asthma & COPD in combination with a long-acting beta2 agonist	II				
	856553	p38 kinase inhibitor (oral)	COPD (also atherosclerosis & rheumatoid arthritis)	II				
	870086	novel glucocorticoid agonist	asthma	II				
	mepolizumab	anti-IL5 monoclonal antibody	severe asthma & nasal polyposis (also hypereosinophilic syndrome & eosinophilic esophagitis)	II				
	Avamys/Allermist	glucocorticoid agonist	allergic rhinitis	Submitted	S:Jul06	S:Jun06		
	Seretide/Advair	beta2 agonist + inhaled corticosteroid	COPD – mortality claim	Submitted	S:Sep06	S:Oct06		
	Ariflo	PDE IV inhibitor (oral)	COPD	Approvable		AL:Oct03		
	Seretide	beta2 agonist + inhaled corticosteroid	asthma – initial maintenance therapy	Approved	A:Jul06	N/A		
	Seretide/Advair	beta2 agonist + inhaled corticosteroid	asthma – non-CFC inhaler	Approved	A:Jun00	A:Jun06		
	Paediatric Vaccines	MenACWY-TT	conjugated	<i>Neisseria meningitidis</i> groups A, C, W & Y disease prophylaxis	II			
		Globorix	conjugated	diphtheria, tetanus, pertussis, hepatitis B, <i>Haemophilus influenzae</i> type b disease, <i>Neisseria meningitidis</i> groups A & C disease prophylaxis	III	2007		
		Hib-MenCY-TT	conjugated	<i>Neisseria meningitidis</i> groups C & Y disease & <i>Haemophilus influenzae</i> type b disease prophylaxis	III			
		Infanrix-IPV	subunit-inactivated	diphtheria, tetanus, pertussis + poliomyelitis prophylaxis (booster-5th dose)	III		2007	
		Synflorix	conjugated	<i>Streptococcus pneumoniae</i> & non-typeable <i>Haemophilus influenzae</i> disease prophylaxis for children	III	2007		
		Priorix-Tetra	live attenuated	measles, mumps, rubella & varicella prophylaxis	Approved	A:Jul06		
		Rotarix [†]	live attenuated – oral	rotavirus induced gastroenteritis prophylaxis	Approved	A:Feb06	2007	
		Other Vaccines	HIV	recombinant	HIV infection prophylaxis	I		
			<i>S. pneumoniae</i> elderly	recombinant-conjugated	<i>Streptococcus pneumoniae</i> disease prophylaxis	I		
Dengue fever			attenuated tetravalent vaccine	Dengue fever prophylaxis	II			
Epstein-Barr virus [†]	recombinant		EBV infection prophylaxis	II				
Hepatitis E virus [†]	recombinant		hepatitis E prophylaxis	II				
Mosquirix	recombinant		malaria prophylaxis	II				
Tuberculosis	recombinant		tuberculosis prophylaxis	II				
Varicella Zoster virus	recombinant		Varicella Zoster prevention	II				
New generation flu vaccine	recombinant split-trivalent		seasonal influenza prophylaxis for the elderly	III				
Simplrix	inactivated		genital herpes prophylaxis	III				
Daronix	inactivated whole-aluminium salt – monovalent		pandemic influenza prophylaxis	Submitted	S:Dec05			
Flu pre-pandemic	H5N1 inactivated split-monovalent		pandemic influenza prophylaxis	Submitted	S:Jan07			
Cervarix [†]	recombinant		human papilloma virus infection prophylaxis	Submitted	S:Mar06	2007		
FluLaval	inactivated split	influenza prophylaxis	Approved	2007	A:Oct06			
Pharmaccines	P501	recombinant	treatment of prostate cancer	I				
	MAGE-A3	recombinant	treatment of non-small cell lung cancer & melanoma	II				

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Product Development Pipeline February 2007

This document outlines GlaxoSmithKline's drug development portfolio. The content of the portfolio will change over time as new compounds progress from research to development and from development to the market.

Owing to the nature of the drug development process, it is not unusual for some compounds, especially those in early stages of investigation, to be terminated as they progress through development.

Phase I	Phase II	Phase III	Filed/Approved
256073	501516 [†]	<i>ambrisentan</i>	<i>Arixtra</i>
568859 [†]	681323	<i>Coreg CR[†] + ACE Inhibitor</i>	<i>Coreg CR[†]</i>
813893	darapladib [†]	<i>Avandamet XR</i>	<i>Avandaryl/Avaglim</i>
856553	189075 [†]	<i>Avandia</i>	<i>Altanax/Altargo</i>
rilapladib [†]	677954	<i>Avandia + simvastatin</i>	<i>Relenza[†]</i>
189075 [†]	869682 [†]	chlorproguanil, dapsone + artesunate (CDA) [†]	<i>Entereg/Entrereg[†]</i>
376501	albiglutide (716155) [†]	<i>Avodart + alpha blocker</i>	<i>Boniva/Bonviva[†]</i>
625019	<i>Avandia</i>	<i>Avodart</i>	<i>Lamictal XR</i>
565154	farglitazar	<i>Avodart</i>	<i>ReQuip extended release</i>
742510	sitamaquine	belimumab [†]	<i>ReQuip Modutab/XL 24 hour</i>
625433	tafenoquine [†]	<i>Entereg/Entrereg[†]</i>	<i>Trexima[†]</i>
825780 [†]	364735 [†]	mepolizumab	<i>Wellbutrin XL/XR[†]</i>
221149	274150	gepirone ER [†]	<i>Tykerb</i>
232802	856553	<i>Lamictal XR</i>	<i>Arranon</i>
267268	876008 [†]	rosiglitazone XR	<i>Hycamtin</i>
315234	casopitant	<i>Tykerb</i>	<i>Avamys/Allermist</i>
366074 [†]	dutosteride + testosterone	casopitant	<i>Seretide/Advair</i>
751689 [†]	<i>HuMax-CD20 (ofatumumab)[†]</i>	<i>HuMax-CD20 (ofatumumab)[†]</i>	<i>Ariflo</i>
768974 [†]	mepolizumab	<i>Hycamtin</i>	<i>Seretide</i>
relacatib [†]	rosiglitazone XR	pazopanib	<i>Priorix-Tetra (v)</i>
163090	solabegron	<i>Promacta (eltrombopag)[†]</i>	<i>Rotarix (v)[†]</i>
189254	372475 [†]	<i>Globorix (v)</i>	<i>Daranrix (v)</i>
239512	468816	Hib-MenCY-TT (v)	Flu pre-pandemic (v)
561679 [†]	649868 [†]	<i>Infanrix-IPV (v)</i>	<i>Cervarix (v)[†]</i>
588045	683699 [†]	<i>Synflorix (v)</i>	<i>FluLaval (v)</i>
598809	742457	New generation flu vaccine (v)	
729327	773812	<i>Simplirix (v)</i>	
823296	842166		
559448 [†]	talnetant	Key	
626616 [†]	pazopanib + <i>Tykerb</i>	(v) Vaccine	
pazopanib	<i>Promacta (eltrombopag)[†]</i>	(p) Pharmaccine	
256066	159797 [†]	† In-license or other alliance relationship with third party	
573719	159802 [†]	S Date of first submission	
961081 [†]	233705	A Date of first regulatory approval (for MAA, this is the first EU approval letter)	
679586	256066	AL Approvable letter indicates that ultimately approval can be given subject to resolution of outstanding queries	
HIV (v)	597901 [†]	MAA Marketing authorisation application (Europe)	
<i>S. pneumoniae</i> elderly (v)	642444 [†]	NDA New drug application (USA)	
P501 (p)	678007 [†]	Phase I Evaluation of clinical pharmacology, usually conducted in volunteers	
	685698	Phase II Determination of dose and initial evaluation of efficacy, conducted in a small number of patients	
	784568	Phase III Large comparative study (compound versus placebo and/or established treatment) in patients to establish clinical benefit and safety.	
	799943		
	870086		
	MenACWY-TT (v)		
	Dengue fever (v)		
	Epstein-Barr virus (v) [†]		
	Hepatitis E (v) [†]		
	<i>Mosquirix (v)</i>		
	Tuberculosis (v)		
	Varicella Zoster (v)		
	MAGE-A3 (p)		

Estimated submission dates are only disclosed where they are within 12 months of the date of the chart. This date represents the most likely year of submission where it is considered that there is a reasonably high probability of successfully meeting the date assuming the clinical data meets the expected end-points of the clinical trials.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

Under the safe harbor provisions of the US Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, including those made in this document, are subject to risks and uncertainties that may cause actual results to differ materially from those projected.

Continued development of commercially viable new products is critical to the Group's ability to replace sales of older products that decline upon expiration of exclusive rights, and to increase overall sales. Developing new products is a costly, lengthy and uncertain process. A new product candidate can fail at any stage of the process, and one or more late-stage product candidates could fail to receive regulatory approval.

New product candidates may appear promising in development but, after significant investments, fail to reach the market or have only limited commercial success as a result of efficacy or safety concerns, inability to obtain necessary regulatory approvals, difficulty or excessive costs to manufacture or infringement of patents or other intellectual property rights of others or inability to differentiate the product adequately from those with which it competes.

Other factors that may affect the Group's operations are described under 'Risk Factors' in the Operating and Financial Review and Prospects in the company's Annual Report on Form 20-F for 2006.

