

Development activities
New Compounds

Development code <generic name>	Drug Class (administration route)	Indications	<i>Stage</i>		In-house/ In-license
TAK-242 <resatorvid>	TLR4 signal transduction inhibitor (injection)	Severe sepsis	Jpn	P-III	In-house
			US	P-III	
			EU	P-III	
TAK-375 <ramelteon>	MT ₁ /MT ₂ receptor agonist (oral)	Insomnia	Jpn	P-III	In-house
		Circadian rhythm sleep disorder (CRSD)	EU	Filed (Mar 07)	
			US	P-II	
TAK-475 * <lapaquistat acetate>	Squalene synthase inhibitor (oral)	Hypercholesterolemia	US	P-III	In-house
			EU	P-III	
			Jpn	P-II	
TAK-390MR <dexlansoprazole>	Proton pump inhibitor (oral)	Erosive esophagitis and non-erosive gastro-esophageal reflux disease	US	Filed (Dec 07)	In-house
				by TAP	
			Jpn	P-II	
SYR-322 <alogliptin>	DPP-4 inhibitor (oral)	Diabetes mellitus	US	Filed (Dec 07)	In-house
			EU	P-III	
			Jpn	P-II	
TAK-491 <->	Angiotensin II receptor blocker (oral)	Hypertension	US	P-III	In-house
			EU	P-III	
Hematide™ <->	Synthetic, peptide-based erythropoiesis-stimulating agent (injection)	Chronic kidney disease related anemia	US	P-III	In-license (Affymax)
		Cancer related anemia	EU	P-III	
			Jpn	P-I/II	
			-	P-I	
TAK-428 <->	Neurotrophic factor production accelerator (oral)	Diabetic neuropathy	US	P-II	In-house
			EU	P-II	
TAK-536 <azilsartan>	Angiotensin II receptor blocker (oral)	Hypertension	US	P-II	In-house
			EU	P-II	
			Jpn	P-II	
TAK-583 <->	Neuropathic pain-improving drug (oral)	Postherpetic neuralgia (PHN)	US	P-II	In-house
			EU	P-II	
		Painful diabetic neuropathy (PDN)	US	P-II	
			EU	P-II	
		Diabetic peripheral neuropathy (DPN)	Jpn	P-II	
			US	P-II	
			EU	P-II	
			Jpn	P-II	
TAK-851 <->	Immune response modifier (topical)	Human papillomavirus (HPV) infection	US	P-II	In-house
			EU	P-II	
EMD72000 <matuzumab>	Humanized, monoclonal antibody (MAb) against the human EGFR (injection)	Gastric cancer, Non-small cell lung cancer (NSLC), Colorectal cancer	US	P-II	In-license (Merck KGaA)
			EU	P-II	
			Jpn	P-II	
ATL-962 <cetilistat>	Lipase inhibitor (oral)	Obesity	Jpn	P-II	In-license (Alizyme)
SYR-472 <->	DPP-4 inhibitor (oral)	Diabetes mellitus	US	P-II	In-house
			EU	P-II	
			Jpn	P-I	

* Regarding TAK-475, clinical studies with higher doses were suspended and the request from the FDA for additional clinical study is under discussion.

TAK-783 < - >	T-cell function regulator (oral)	Rheumatoid arthritis	US EU Jpn	P-II P-II P-I	In-house
Lu AA21004 < - >	Bis-aryl-sulphonyl amine (oral)	Mood and anxiety disorders	EU	P-III	In-license (Lundbeck)
Lu AA24530 < - >	Monoamine modulator (oral)	Mood and anxiety disorders	EU	P-II	In-license (Lundbeck)
SNT-MC17 < idebenone >	Mitochondria targeted anti-oxidant (oral)	Friedreich's ataxia Duchenne muscular dystrophy	EU EU	Filed (Aug 07) P-II	In-license (Santhera)
TAK-442 < - >	Factor X (FXa) inhibitor (oral)	Venous / arterial thromboembolism	US EU	P-II P-II	In-house
TAK-085 < - >	EPA/DHA agent (oral)	Hypertriglyceridemia	Jpn	P-II	In-license (Pronova)
TAK-379 < - >	Insulin sensitizer (oral)	Diabetes mellitus	-	P-I	In-house
TAK-100 < - >	DPP-4 inhibitor (oral)	Diabetes mellitus	-	P-I	In-house
TAK-591 < - >	Angiotensin II receptor blocker (oral)	Hypertension	-	P-I	In-house
TAK-700 < - >	Sex hormone synthesis inhibitor (oral)	Prostate cancer	-	P-I	In-house
CBP-501 < - >	G2 checkpoint abrogater (injection)	Malignant mesothelioma, Lung cancer	-	P-I	In-license (CanBas)
TAK-285 < - >	HER2 inhibitor (oral)	Solid tumors	-	P-I	In-house
TAK-683 < - >	GnRH modulator (injection)	Prostate cancer	-	P-I	In-house
TAK-065 < - >	Neuroregeneration enhancer (oral)	Alzheimer disease, Parkinson's disease	-	P-I	In-house
TAK-385 < - >	LH-RH receptor antagonist (oral)	Endometriosis, Uterus myoma	-	P-I	In-house
TAK-438 < - >	Potassium-competitive acid blocker (oral)	Acid-related diseases (GERD, Peptic ulcer disease etc)	-	P-I	In-house
TAK-363 < - >	Bladder hypersensitivity suppression (Suppression of micturition reflex) (oral)	Frequent urination, Urinary incontinence (Overactive bladder)	-	P-I	In-license (Toray)

Additional indications/new formulations

Development code <generic name> Brand name (country / region)	Drug Class	Indications or formulations	Stage	In-house / In-license
SPI-0211 <lubiprostone>	Chloride channel opener (oral)	Irritable bowel syndrome with constipation Opioid-Induced bowel dysfunction (OBD)	US Filed (Jun 07) US P-III	In-license (Sucampo)
TAP-144-SR <leuprorelin acetate> Leuplin (Jpn) Lupron Depot (U.S.) Enantone, etc. (EU , Asia)	LH-RH agonist	6-month depot/prostate cancer	EU (Ger) Filed (Jun 05) EU (Ita) Filed (Oct 05) EU (Fra) Filed (Nov 05)	In-house
AG-1749 <lansoprazole> Takepron (Jpn, Asia) Prevacid (U.S., Asia) Ogast, Agopton, Lansox, etc. (EU)	Proton pump inhibitor	Risk reduction of NSAID-associated gastric ulcer	Jpn P-III	In-house
TCV-116 <candesartan cilexetil> Bliopress (Jpn, EU, Asia) Amias, Kenzen, etc. (EU)	Angiotensin II receptor blocker	Fixed dose combination with diuretic High dose Outcome study: DIRECT Diabetic REtinopathy Candesartan Trial	Jpn P-III EU P-III Jpn P-III EU P-III	In-house
AD-4833 <pioglitazone> Actos (Jpn, U.S., EU, Asia)	Insulin sensitizer	Combination drug of Actos / Metformin XT Delay in progression of Atherosclerosis Concomitant therapy with metformin Concomitant therapy with insulin Fixed dose combination with SYR-322	US Filed (Mar 06) US P-III Jpn Filed (Jan 07) Jpn Filed (Jun 07) US P-III EU P-III	In-house
AO-128 <voglibose> Basen (Jpn, Asia)	Alpha-glucosidase inhibitor	Prevention of onset of type 2 diabetes in patients with impaired glucose tolerance (IGT)	Jpn Filed (Dec 07)	In-house
KAD-1229 <mitiglinide> Glufast (Jpn)	Short-acting insulin secretagogue	Concomitant therapy with insulin sensitizer	Jpn Filed (Apr 07)	In-license (Kissei)
NE-58095 <risedronate> Benet (Jpn)	Bone resorption inhibitor	Paget's disease of bone	Jpn Filed (Jul 07)	In-license (Ajinomoto)

Recent progress in stage *

Development code	Indications	country/region	Progress in stage
TAK-442	Venous / arterial thromboembolism	US, EU	P-II
AO-128	Impaired glucose tolerance (IGT)	Jpn	Filed (Dec 07)
Lu AA21004	Mood and anxiety disorders	EU	P-III
SYR-322	Diabetes mellitus	US	Filed (Dec 07)
TAK-390MR	Erosive esophagitis and non-erosive gastro-esophageal reflux disease	US Jpn	Filed (Dec 07) P-II
TAK-085	Hypertriglyceridemia	Jpn	P-II

Discontinued project *

Development code	Indications (stage)	Reason
TAK-375	Alzheimer's sleep / wake disturbance (P-III)	The number of enrolled patients meeting inclusion criteria did not reached an expected level.

<*Update after 1st half FY07 results (November 5)>