

R&D Pipeline (May 2007)

1.Japan

(1)Filed

Code No.	Generic Name (Filing Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM060	ramosetron (Jan. 2006)	Irritable bowel syndrome (IBS)	5-HT ₃ receptor antagonist	Oral	In-house	New indication
YM026	nateglinide (Jan. 2006)	Type 2 diabetes (concomitant treatment with biganides)	Rapid onset insulin secretion enhancer	Oral	Ajinomoto	New indication
FK506	tacrolimus (May 2006)	Suppression of organ rejection in organ transplant (modified release)	Immunosuppressant	Oral	In-house	New formulation
T-3811	garenoxacin (May 2006)	Respiratory infections and otolaryngologic infections	Quinolone antibiotic	Oral	Toyama	
YM086 (BIBR277)	telmisartan (June 2006)	Type 2 diabetic nephropathy	Angiotensin II receptor blocker	Oral	Boehringer Ingelheim	New indication
YM529	minodronate (July 2006)	Osteoporosis	Bisphosphonate	Oral	In-house	
YM026	nateglinide (Nov.2006)	Type 2 diabetes (concomitant treatment with insulin sensitizers)	Rapid onset insulin secretion enhancer	Oral	Ajinomoto	New indication
BIBR277HCT	telmisartan/ hydrochlorothizide (April 2006)	Hypertension	Combination drug of angiotensin II receptor blocker / diuretic	Oral	Boehringer Ingelheim	Combination drug
YM177	celecoxib (Feb. 2007)	Low back pain, shoulder peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis	Cyclooxygenase-II inhibitor	Oral	Pfizer	New indication
YM1170	famotidine (Feb. 2007)	Non-erosive reflux disease (NERD)	H ₂ receptor antagonist	Oral	In-house	New indication

(2)Phase-III

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM617	tamsulosin	Lower urinary tract syndrome	Alpha-1 receptor antagonist	Oral	In-house	New indication
YM177	celecoxib	Post surgical pain, post traumatic pain, tooth extraction pain	Cyclooxygenase-II inhibitor	Oral	Pfizer	New indication
FK506	tacrolimus	Ulcerative colitis	Immunosuppressant	Oral	In-house	New indication
FK506	tacrolimus	Myasthenia gravis (all)	Immunosuppressant	Oral	In-house	New indication
FK199B	zolpidem	Insomnia (modified release)	Omega-1 receptor agonist	Oral	Sanofi Aventis	New formulation

(3)Phase-II

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM974	valdecoxib	Rheumatoid arthritis, osteoarthritis, low back pain, etc.	Cyclooxygenase-II inhibitor	Oral	Pfizer	
YM978	parecoxib	Acute pain	Cyclooxygenase-II inhibitor	Injection	Pfizer	
YM533	beraprost sodium	Chronic renal failure (primary / nephrosclerosis)	Prostacyclin receptor stimulator	Oral	Toray	New indication New formulation
YM150		Prevention of venous thromboembolism (VTE) after major orthopedic surgery, prophylaxis of thromboembolic complications associated with atrial fibrillation(AF)	Factor Xa inhibitor	Oral	In-house	
ASP2151		Herpes zoster, genital herpes	Helicase-primase inhibitor	Oral	In-house	
ASP8825 (XP13512)		Restless leg syndrome, painful diabetic neuropathy	Prodrug of gabapentin	Oral	XenoPort	

2.USA

(1)Approved

Product Name (Code No.)	Generic Name (Approval Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
Vaprisol (YM087)	conivaptan (Feb. 2007)	Hypervolemic hyponatremia	Vasopressin receptor antagonist	Injection	In-house	New indication

(2)Filed

Code No.	Generic Name (Filing Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
FK506(*)	tacrolimus (Dec. 2005)	Suppression of organ rejection in organ transplant (modified release)	Immunosuppressant	Oral	In-house	New formulation
FK506(**)	tacrolimus (Feb. 2006)	Use of Prograf and MMF as an adjunct therapy for the prophylaxis of organ rejection in kidney transplantation	Immunosuppressant	Oral	In-house	New indication
	telavancin (Dec. 2006)	Complicated skin and skin structure infections (cSSSI)	Lipoglycopeptide antibiotic	Injection	Theravance	
RSD1235	vernakalant (Dec. 2006)	Atrial fibrillation(AF)	Antiarrhythmic agent	Injection	Cardiome	
FK463	micafungin (Dec. 2006)	Candidemia and other <i>candida</i> infections	Candin antifungal agent	Injection	In-house	New indication

*FK506(modified release): Received an action letter from the FDA in January 2006. "Approvable" for kidney and liver transplant, and "not approvable" for heart transplant.

**FK506: Received approvable letter from the FDA in March 2007

(3)Phase-III

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
FK506	tacrolimus	Atopic dermatitis	Immunosuppressant	Cream	In-house	New indication New formulation
CVT-3146	regadenoson	Pharmacologic stress agent in cardiac perfusion imaging studies	Adenosine A _{2a} agonist	Injection	CV Therapeutics	
FK506	tacrolimus	Psoriasis	Immunosuppressant	Cream	In-house	New indication New formulation
	telavancin	Hospital-acquired pneumonia (HAP)	Lipoglycopeptide antibiotic	Injection	Theravance	
YM617	tamsulosin	Pediatric neurogenic bladder	Alpha-1 receptor antagonist	Oral	In-house	New indication

(4)Phase-II

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM443		Functional dyspepsia	Acetylcholine level enhancer	Oral	Zeria	
YM155		Hormone refractory prostate cancer, non small cell lung cancer, metastatic melanoma, etc.	Survivin suppressant	Injection	In-house	
YM672 (IPD-1151T)	suplatast tosilate	Interstitial cystitis	anti-allergy agent	Oral	Taiho	
YM758		Atrial fibrillation(AF)	Cardiac I _f channel inhibitor	Oral	In-house	
YM150		Prophylaxis of thromboembolic complications associated with atrial fibrillation(AF)	Factor Xa inhibitor	Oral	In-house	
ASP2151		Herpes zoster, genital herpes	Helicase-primase inhibitor	Oral	In-house	

3.Europe

(1)Approved

Product Name (Code No.)	Generic Name (Approval Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
Advagraf (FK506)	tacrolimus (April 2007)	Suppression of organ rejection in organ transplant (modified release)	Immunosuppressant	Oral	In-house	New formulation

(2)Filed

Code No.	Generic Name (Filing Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
FK463	micafungin (April 2006)	Deep-seated fungal infection	Candin antifungal agent	Injection	In-house	
	telavancin (April 2007)	Complicated skin and soft tissue infections (cSSTI)	Lipoglycopeptide antibiotic	Injection	Theravance	

(3)Phase-III

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
	telavancin	Hospital-acquired pneumonia (HAP)	Lipoglycopeptide antibiotic	Injection	Theravance	

(4)Phase-II

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM178		Urinary frequency, urinary incontinence or urgency associated with overactive bladder	Beta 3 receptor agonist	Oral	In-house	
YM150		Prevention of venous thromboembolism (VTE) after major orthopedic surgery, prophylaxis of thromboembolic complications associated with atrial fibrillation(AF)	Factor Xa inhibitor	Oral	In-house	
YM060	ramosetron	Irritable bowel syndrome (IBS)	5-HT ₃ receptor antagonist	Oral	In-house	
YM155		Hormone refractory prostate cancer, non small cell lung cancer, metastatic melanoma, etc.	Survivin suppressant	Injection	In-house	
YM672 (IPD-1151T)	suplatast tosilate	Interstitial cystitis	anti-allergy agent	Oral	Taiho	
YM311 (FG-2216)		Renal anemia, chemotherapy-induced anemia	HIF stabilizer	Oral	FibroGen	
YM758		Stable angina	Cardiac I _f channel inhibitor	Oral	In-house	
YM543		Type 2 diabetes	SGLT2 inhibitor	Oral	Kotobuki	

4.Projects at Early Stage (Phase-I/Pre-clinical): 31

Changes from the previous announcement (Financial results announcement for 3Q of FY2006 on February 1, 2007)

- Vaprisol (YM087) for the treatment of hypervolemic hyponatremia was approved in the US (February 2007).
- Advagraf (FK506 modified release) for the treatment of suppression of organ rejection in organ transplant was approved in Europe (April 2007).
- sNDA for YM177 for the treatment of low back pain, shoulder peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis was filed in Japan (February 2007).
- sNDA for YM1170 for the treatment of non-erosive reflux disease was filed in Japan (February 2007).
- Approvable letter from the FDA for the sNDA for the use of Prograf and MMF as an adjunct therapy for the prophylaxis of organ rejection in kidney

transplantation was received (March 2007).

- MAA for telavancin for the treatment of complicated skin and soft tissue infections was filed in Europe (April 2007).
- YM150 for the treatment of prophylaxis of thromboembolic complications associated with atrial fibrillation entered Phase-II in Japan
- ASP2151 for the treatment of herpes zoster and genital herpes entered Phase-II in Japan.
- ASP8825 (XP13512) for the treatment of restless leg syndrome and painful diabetic neuropathy entered Phase-II in Japan