R&D Pipeline (May 2008)

1.Global development

(1) Approval

Code No. Generic Name	Product Name (Approval Date)	Classification	Therapeutic Target	Area	Dosage Form	Origin	Remarks
FK463 micafungin	Mycamine (April 2008)	Candin antifungal agent	Treatment of Invasive candidiasis Treatment of oesophageal candidiasis Prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation	Europe	Injection	In-house	

(2) Filed-1

Stage in the Most Advanced Territory

Code No. Generic Name	Classification	Therapeutic Target	Area / Phase	Dosage Form	Origin	Remarks
FK506 tacrolimus	Immunosuppressant	Suppression of organ rejection in organ transplant (modified release)	Japan Filed (May 2006)	Oral	In-house	New formulation
			USA Filed (Dec. 2005) *			
		Use of FK506 and MMF as an adjunct therapy for the prophylaxis of organ rejection in kidney transplantation	USA Filed (Feb. 2006) **	Oral	In-house	New indication
		Suppression of organ rejection in organ transplant (granules)	Europe Filed (Nov. 2007)	Oral	In-house	New formulation
		Atopic dermatitis (Prophylaxis of relapse)	Europe Filed (Jan. 2008)	Ointment	In-house	New indication

*FK506(modified release): Received an action letter from the FDA in January 2007; “Approvable” for liver and kidney and “not approvable” for heart transplant. Received second action letters from the FDA; “Approvable” for kidney and Liver in March and April 2008, respectively.

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

(2) Filed-2

Stage in the Most Advanced Territory

Code No. Generic Name	Classification	Therapeutic Target	Area / Phase	Dosage Form	Origin	Remarks
FK506	Immunosuppressant	Ulcerative colitis	Japan Phase-III	Oral	In-house	New indication
		Myasthenia gravis (all)	Japan Phase-III	Oral	In-house	New indication
		Atopic dermatitis	USA Phase- III	Cream	In-house	New indication New formulation
		Psoriasis	USA Phase-III	Cream	In-house	New indication New formulation
YM060 ramosetron	5-HT_3 receptor antagonist	Irritable bowel syndrome (IBS)	Japan Filed (Jan. 2006)	Oral	In-house	New indication
			Europe Phase-II	Oral	In-house	
YM617 tamsulosin	Alpha-1 receptor antagonist	Lower urinary tract syndrome in male patients	Japan Filed (June 2007)	Oral	In-house	New indication
		Pediatric neurogenic bladder	USA Phase-III	Oral	In-house	New indication
telavancin	Lipoglycopeptide antibiotic	Complicated skin and skin structure infections (cSSSI)	USA Filed (Dec. 2006) ***	Injection	Theravance	
			Europe Filed (April 2007)	Injection	Theravance	
		Hospital-acquired pneumonia (HAP)	USA Phase-III Europe Phase-III	Injection	Theravance	
		MRSA infections	Japan Phase-I	Injection	Theravance	

***telavancin: Received an approvable letter from the FDA in October 2007

(3) Phase-III/ Phase-II-1

Stage in the Most Advanced Territory

Code No. Generic Name	Classification	Therapeutic Target	Area / Phase	Dosage Form	Origin	Remarks
YM178	Beta 3 receptor agonist	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	USA Phase-III Europe Phase-III Japan Phase-II	Oral	In-house	
YM150	Factor Xa inhibitor	Prevention of venous thromboembolism (VTE) after major orthopedic surgery	Europe Phase-II USA Phase-II Japan/Asia Phase-II	Oral	In-house	
		Prophylaxis of thromboembolic complications associated with atrial fibrillation (AF)	Europe Phase-II Japan/Asia Phase-II			
YM443	Acetylcholine esterase inhibitor	Functional dyspepsia	Japan Phase-III USA Phase-II	Oral	Zeria	
YM155	Survivin suppressant	Hormone refractory prostate cancer, Non-small cell lung cancer, Metastatic melanoma, Non-Hodgkin's lymphoma	USA Phase-II Europe Phase-II Japan Phase-I	Injection	In-house	
ASP2151	Helicase-primase inhibitor	Herpes zoster, Genital herpes	Japan Phase-II USA Phase-II	Oral	In-house	
ASP0485 alefacept	Immunosuppressant	Prophylaxis of kidney transplant rejection	USA Phase-II Europe Phase-II	Injection	In-house	
YM543	SGLT2 inhibitor	Type 2 diabetes	Europe Phase-II	Oral	Kotobuki (co-development)	
ASP1941	SGLT2 inhibitor	Type 2 diabetes	Japan Phase-II USA Phase-II	Oral	Kotobuki (co-development)	
ASP9831	PDE4 inhibitor	Non-alcoholic steatohepatitis	Europe Phase-II	Oral	In-house	

(3) Phase-III/ Phase-II-2

Stage in the Most Advanced Territory

Code No. Generic Name	Classification	Therapeutic Target	Area / Phase	Dosage Form	Origin	Remarks
YM311 (FG-2216)	HIF stabilizer	Renal anemia	Europe Phase-II Japan Phase-I	Oral	FibroGen	
ASP1517 (FG-4592)	HIF stabilizer	Renal anemia	Europe Phase-II	Oral	FibroGen	
solifenacin/ tamsulosin	Co-administration of solifenacin and tamsulosin	Lower urinary tract syndrome associated with benign prostatic hyperplasia (BPH)	Europe Phase-II	Oral	In-house	

2.Local development: Japan

(1) Filed

Most Advanced Stage

Code No. Generic Name	Classification	Therapeutic Target	Area / Phase	Dosage Form	Origin	Remarks
BIBR277HCT telmisartan/ hydrochlorothiazide	Combination drug of angiotensin II receptor blocker / diuretic	Hypertension	Japan Filed (April 2006)	Oral	Boehringer Ingelheim	Combination drug
YM086 (BIBR277) telmisartan	Angiotensin II receptor blocker	Type 2 diabetic nephropathy	Japan Filed (June 2006)	Oral	Boehringer Ingelheim	New indication
YM529 minodronate	Bisphosphonate	Osteoporosis (once daily)	Japan Filed (July 2006)	Oral	In house (co-development with Ono)	
		Osteoporosis (intermittent administration)	Japan Phase-I			
YM026 nateglinide	Rapid onset insulin secretion enhancer	Type 2 diabetes (concomitant treatment with insulin sensitizers)	Japan Filed (Nov.2006)	Oral	Ajinomoto	New indication
YM177 celecoxib	Cyclooxygenase-II inhibitor	Low back pain, Shoulder periarthritis, Cervico-omo-brachial syndrome and Tenosynovitis	Japan Filed (Feb. 2007)	Oral	Pfizer	New indication
		Acute pain	Japan Phase-III			

(2) Phase-III/ Phase-II

Most Advanced Stage

Code No. Generic Name	Classification	Therapeutic Target	Area / Phase	Dosage Form	Origin	Remarks
FK199B zolpidem	Omega-1 receptor agonist	Insomnia (modified release)	Japan Phase-III	Oral	sanofi aventis	New formulation
YM533 beraprost sodium	Prostacyclin receptor stimulator	Chronic renal failure (primary / nephrosclerosis)	Japan Phase-II	Oral	Toray	New indication New formulation
ASP8825 (XP13512)	Prodrug of gabapentin	Restless legs syndrome, Painful diabetic neuropathy	Japan Phase-II	Oral	XenoPort	
ASP1585 (AMG223)	Non-absorbed, polymer-based phosphate binder	Hyperphosphatemia	Japan Phase-II	Oral	Ilypsa/Amgen	
ASP3550 degarelix	GnRH receptor antagonist	Prostate cancer	Japan Phase-II	Injection	Ferring	

3.Local development: USA

(1) Approval

Code No. Generic Name	Product Name (Approval Date)	Classification	Therapeutic Target	Area	Dosage Form	Origin	Remarks
CVT-3146 regadenoson	Lexiscan (April 2008)	$A2_A$ adenosine receptor agonist	Pharmacologic stress agent for radionuclide MPI studies in patients unable to undergo adequate exercise stress	USA	Injection	CV Therapeutics	

(2) Filed

Code No. Generic Name	Classification	Therapeutic Target	Area / Phase	Dosage Form	Origin	Remarks
RSD1235 vernakalant	Atrial fibrillation (AF)	Antiarrhythmic agent	USA Filed (Dec. 2006)	Injection	Cardiome	
YM087 conivaptan	V1a/V2 receptor antagonist	Hyponatremia (Pre-mix bag formulation)	USA Filed (Mar. 2008)	Injection	In-house	New formulation

4.Phase-I (new disclosure)

Code No. Generic Name	Therapeutic Target	Dosage Form	Origin
ASP0265	Prostate cancer, Endometriosis	Oral	In-house
ASK8007	Rheumatoid arthritis	Injection	IBL Kaketsuken (co-development)
ASP2535	Alzheimer's disease Schizophrenia	Oral	In-house
ASP2314	Schizophrenia	Oral	NeuroSearch
ASP2905	Alzheimer's disease Schizophrenia	Oral	In-house

5.Projects Discontinued

Code No. Generic Name	Area / Phase	Therapeutic Target	Reason
YM974 valdecoxib	Japan Phase-II	Rheumatoid arthritis, Osteoarthritis, Low back pain, etc.	In consideration of the anticipated difficulty of obtaining regulatory approval given the withdrawal of the product from other markets, discontinuation of development was decided.
YM978 parecoxib	Japan Phase-II	Acute pain	In consideration of potential difficulties in development and limited financial opportunity in acute pain, discontinuation of development was decided.

Changes from the previous announcement (Financial results announcement for third quarter of FY2007 on February 1, 2008)

- FK463 NDA was approved in Europe.
- CVT-3146 was approved in the US.
- YM087 conivaptan (Pre-mix bag formulation) was filed in the US.
- YM178 entered Phase-III in the US and Europe.
- YM443 entered Phase-III in Japan.
- ASP1941 entered Phase-II in the US.
- ASP1517 (FG-4592) entered Phase-II in Europe.
- YM974 was discontinued in Japan.
- YM978 was discontinued in Japan.