

R&D Pipeline (May 2006)

1. Japan

(1) Approved

Product Name (Code No.)	Generic Name (Approval Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
Vesicare (YM905)	solifenacin (April 2006)	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	Muscarinic receptor antagonist	Oral	In-house	
Funguard (FK463)	miconazole (April 2006)	Deep-seated fungal infection (for pediatric)	Candidin antifungal agent	Injection	In-house	New indication

(2) Filed

Code No.	Generic Name (Filing Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM177	celecoxib (Dec. 2002)	Rheumatoid arthritis, osteoarthritis, low back pain, etc.	Cyclooxygenase-II inhibitor	Oral	Pfizer	
YM152	finasteride (Dec.1994)	Benign prostatic hyperplasia	5 alpha-reductase inhibitor	Oral	Merck	
FK506	tacrolimus (Oct. 2005)	Lupus nephritis	Immunosuppressant	Oral	In-house	New indication
YM060	ramosetron (Jan. 2006)	Irritable bowel syndrome (IBS)	5-HT ₃ antagonist	Oral	In-house	New indication
YM026	nateglinide (Jan. 2006)	Type II diabetes (concomitant treatment with biganides)	Rapid onset insulin secretion enhancer	Oral	Ajinomoto	New indication
FK463	miconazole (Jan. 2006)	Deep-seated fungal infection (Prophylaxis of <i>Aspergillus</i> and <i>Candida</i> infections in patients undergoing hematopoietic stem cell transplantation)	Candidin antifungal agent	Injection	In-house	New indication

(3)Preparation for Filing

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
T-3811	garenoxacin	Respiratory infections and otolaryngologic infections	Quinolone antibiotic	Oral	Toyama	
FK506	tacrolimus	Suppression of organ rejection in organ transplant (modified release)	Immunosuppressant	Oral	In-house	New formulation

(4)Phase-III

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM529	minodronate	Osteoporosis	Bisphosphonate	Oral	In-house	
YM617	tamsulosin	Lower urinary tract syndrome	Alpha-1 receptor antagonist	Oral	In-house	New indication
YM643	interferon alfacon-1	Chronic hepatitis C virus infection (advaferon for use in combination with ribavirin)	Consensus interferon (CIFN)	Injection/ ribavirin: Oral	Schering-Plough	New indication
YM086	telmisartan	Diabetic nephropathy	Angiotensin II receptor antagonist	Oral	Boehringer Ingelheim	New indication
YM026	nateglinide	Type II diabetes (concomitant treatment with insulin sensitizers)	Rapid onset insulin secretion enhancer	Oral	Ajinomoto	New indication
YM177	celecoxib	Post surgical pain, post traumatic pain, tooth extract pain	Cyclooxygenase-II inhibitor	Oral	Pfizer	New indication
FK506	tacrolimus	Ulcerative colitis	Immunosuppressant	Oral	In-house	New indication
	telithromycin	Pediatric use	Ketolide class antibiotic	Oral	Sanofi Aventis	New indication
YM1170	famotidine	Symptomatic-gastro-esophageal reflux disease (S-GERD)	H ₂ receptor antagonist	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

(5)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	
FK481	strontium ranelate	Osteoporosis	Bone formation stimulating and antiresorptive agent	Oral	Servier	
YM533	beraprost	Chronic renal failure (primary / nephrosclerosis)	Prostacyclin receptor stimulator	Oral	Toray	New indication New formulation

2.USA**(1)Filed**

Code No.	Generic Name (Filing Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM087(*)	conivaptan (Jan.2004)	Hypervolemic hyponatremia	Vasopressin receptor antagonist	Injection	In-house	
FK506	tacrolimus (Dec. 2005)	Suppression of organ rejection in organ transplant (modified release)	Immunosuppressant	Oral	In-house	New formulation
RSD1235	(March 2006)	Atrial fibrillation	Antiarrhythmic agent	Injection	Cardiome	

* YM087:Received approvable letter from FDA in December, 2005

(2)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	Complicated skin and skin structure infections (cSSSI), hospital-acquired pneumonia (HAP)	Lipoglycopeptide antibiotic	Injection	Theravance	

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM617	tamsulosin	Pediatric neurogenic bladder	Alpha-1 receptor antagonist	Oral	In-house	New indication

(3)Phase-II

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM443		Functional dyspepsia	Acetylcholine level enhancer	Oral	Zeria	
FK778		Suppression of organ rejection in liver and kidney transplants	Immunosuppressant	Oral	Sanofi Aventis	
	carperitide	Acute heart failure	Alfa-human atrial natriuretic peptide	Injection	Daiichi Asbio	
FK962		Alzheimer's disease	Antidementia	Oral	In-house	
YM155		Hormone refractory prostate cancer, non small cell lung cancer, metastatic melanoma, etc.	Survivin expression inhibitor	Injection	In-house	
FK506	tacrolimus	Asthma	Immunosuppressant	Inhalation	In-house	New indication New formulation
YM672 (IPD-1151T)	suplatast tosilate	Interstitial cystitis	anti-allergy agent	Oral	Taiho	

3.Europe

(1)Filed

Code No.	Generic Name (Filing Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
FK506	tacrolimus (Jan, 2006)	Suppression of organ rejection in organ transplant (modified release)	Immunosuppressant	Oral	In-house	New formulation
FK463	micafungin (April 2006)	Deep-seated fungal infection	Candin antifungal agent	Injection	In-house	New formulation

(2)Phase-III

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
	telavancin	Complicated skin and skin structure infections (cSSSI), hospital-acquired pneumonia (HAP)	Lipoglycopeptide antibiotic	Injection	Theravance	

(3)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 antagonist	Oral	In-house	
YM617	tamsulosin	Functional symptoms with benign prostatic hyperplasia	Alpha-1 receptor antagonist	Oral	In-house	Orally disintegrating tablet
FK778		Suppression of organ rejection in liver and kidney transplants	Immunosuppressant	Oral	Sanofi Aventis	
FK506	tacrolimus	Asthma	Immunosuppressant	Inhalation	In-house	New indication New formulation
YM155		Hormone refractory prostate cancer, non small cell lung cancer, metastatic melanoma, etc.	Survivin expression inhibitor	Injection	In-house	
YM672 (IPD-1151T)	suplatast tosilate	Interstitial cystitis	anti-allergy agent	Oral	Taiho	
FG-2216/ YM311		Renal anemia, chemotherapy-induced anemia	HIF stabilizer	Oral	FibroGen	

4. Projects at Early Stage (Phase-I/Pre-clinical): 28

5. Project Discontinued

Code No.	Stage	Therapeutic Target	Reason
FK949	P-II (Japan)	Behavioral and psychological symptoms of dementia	The development of FK949 for treatment of Alzheimer's disease in Japan has been discontinued based on efficacy observations in Phase II trials in behavioral and psychological symptoms of dementia in Japanese Alzheimer's patients.
FK506	P-III (USA) P-II (Europe)	Rheumatoid arthritis	Though clinical data indicated efficacy of FK506 for the treatment of rheumatoid arthritis, Astellas ceased the development for this indication in the US and Europe upon the total evaluation including product positioning and competition.

Changes from the previous announcement (Financial results announcement for 3Q of FY2005 in January, 2006)

- Vesicare (YM905) for the treatment of urinary frequency, urinary incontinence or urgency associated with overactive bladder was approved in Japan.
- Funguard (FK463) for the treatment of deep-seated fungal infection for pediatric was approved in Japan.
- NDA of RSD1235 for the treatment of atrial fibrillation was filed in the US.
- NDA of FK463 for the treatment of deep-seated fungal infection was filed in Europe.
- Development status of FK506 modified release for the treatment of suppression of organ rejection in organ transplant was progressed from Phase-II to in preparation for NDA in Japan.
- Phase-III of FK199B (modified release) for the treatment of Insomnia was initiated in Japan.
- Development status of FG-2216/YM311 for the treatment of renal anemia and chemotherapy-induced anemia is Phase-II in Europe.
- Vaprisol (YM087) for the treatment of euvolemic hyponatremia was launched in the US and removed from the pipeline.
- Phase-II of FK949 for the treatment of behavior psychological symptoms of dementia was discontinued in Japan.
- Phase-III in the US and Phase-II in Europe of FK506 for the treatment of rheumatoid arthritis was terminated, respectively.