

R&D Pipeline (May 2005)

1. Japan

(1) Approved

Code No. (Product Name)	Generic Name (Approved Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM617 (Harnal D)	tamsulosin (Sep.2004)	Functional symptoms with benign prostatic hyperplasia	Alpha-1 receptor antagonist	Oral	In-house	Orally disintegrating tablet

(2) Filed

Code No.	Generic Name (Filing Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM905	solifenacin (Aug. 2004)	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	Muscarinic receptor antagonist	Oral	In-house	
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	
	fluvoxamine maleate (July. 2003)	Social anxiety disorder	Antidepressant	Oral	Solvay	New indication
FK506	tacrolimus (Jan. 2004)	Ulcerative colitis	Immunosuppressant	Oral	In-house	New indication
	telithromycin	Skin and soft tissue infections & uterine infection	Ketolide class antibiotic	Oral	Sanofi Aventis	New indication
FK463	miconazole (July. 2004)	Deep-seated fungal infection (for pediatric)	Candin antifungal agent	Injection	In-house	New indication

(3)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
YM086	telmisartan	Diabetic nephropathy	Angiotensin II receptor antagonist	Oral	Boehringer Ingelheim	New indication
YM643	interferon alfacon-1	Chronic hepatitis C virus infection (Advaferon for use in combination with ribavirin)	Consensus interferon (CIFN)	Injection/ ribavirin: Oral	Amgen Schering-Plough	New indication
YM060	ramosetron	Irritable bowel syndrome (IBS)	5HT3 antagonist	Oral	In-house	New indication
YM026	nateglinide	Type II diabetes (Concomitant treatment with Biganides)	Rapid onset insulin secretion enhancer	Oral	Ajinomoto	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	Lupus nephritis	Immunosuppressant	Oral	In-house	New indication
	telithromycin	Pediatric use	Ketolide class antibiotic	Oral	Sanofi Aventis	New indication

(4)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	
FK614		Non-insulin dependent diabetes mellitus (NIDDM)	Insulin sensitizer	Oral	In-house	
FK352B		Dialysis-related hypotension	Adenosine A1 antagonist	Injection	In-house	
FK949	quetiapine fumarate	Behavior psychological symptoms of dementia	Antipsychotic	Oral	AstraZeneca	New indication

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
FK481	strontium ranelate	Osteoporosis	Bone formation stimulating and antiresorptive agent	Oral	Servier	
FK506	tacrolimus	Suppression of organ rejection in organ transplant (modified release)	Immunosuppressant	Oral	In-house	New formulation

2.USA

(1)Filed

Code No. (Product Name)	Generic Name (Filing Date)	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM087	conivaptan (Jan.2004)	Hyponatremia	Vasopressin receptor antagonist	Injection	In-house	
(Aczone™)	dapsone (Aug. 2004)	Acne	Antibiotic and antiphlogistic agent	gel	QLT	

*YM087: Received Approvable letter from FDA in November, 2004

(2)Phase-III

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
FK506	tacrolimus	Rheumatoid arthritis	Immunosuppressant	Oral	In-house	New indication
FK506	tacrolimus	Atopic dermatitis	Immunosuppressant	Cream	In-house	New indication New formulation
RSD1235		Atrial fibrillation and atrial flutter	Antiarrhythmic agent	Injection	Cardiome	
CVT-3146	regadenoson	Pharmacologic stress agent in cardiac perfusion imaging studies	Adenosine A _{2a} agonist	Injection	CV Therapeutics	

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
FK506	tacrolimus	Psoriasis	Immunosuppressant	Gel/Cream	In-house	New indication New formulation
FK506	tacrolimus	Suppression of organ rejection in organ transplant (modified release)	Immunosuppressant	Oral	In-house	New formulation

(3)Phase-II

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM443		Functional dyspepsia	Acetylcholine level enhancer	Oral	Zeria	
FK614		Non-insulin dependent diabetes mellitus (NIDDM)	Insulin sensitizer	Oral	In-house	
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 Suntory	
FK962		Alzheimer's disease	Antidementia	Oral	In-house	

3.Europe

(1)Preparation for Filing

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
FK463	micafungin	Deep-seated fungal infection	Candin antifungal agent	Injection	In-house	

(2)Phase-III

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

(3)Phase-II

Code No.	Generic Name	Therapeutic Target	Classification	Dosage Form	Origin	Remarks
YM178		Overactive bladder	Beta 3 receptor agonist	Oral	In-house	
YM150		Prevention of deep vein thrombosis (DVT), Prevention of thromboembolism in atrial fibrillation	Factor Xa inhibitor	Oral	In-house	
YM060	ramosetron	Irritable bowel syndrome (IBS)	5HT3 antagonist	Oral	In-house	
YM617	tamsulosin	Functional symptoms with benign prostatic hyperplasia	Alpha-1 receptor antagonist	Oral	In-house	Orally disintegrating tablet
FK506	tacrolimus	Rheumatoid arthritis	Immunosuppressant	Oral	In-house	New indication
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

4.Projects at Early Stage(Phase-I/Pre-clinical): 25**5.Project Discontinued**

Code No.(Generic Name)	Stage	Therapeutic Target	Reason
YM087(conivaptan)	P-II(EU/USA)	Acutely decompensated chronic heart failure (New indication)	Expected effects were not achieved.

Changes from the previous announcement (3rd Quarter Business Results for FY2004)

- Yamanouchi Pharmaceutical Co., Ltd. and Nippon Kayaku Co, Ltd. reached a licensing agreement that grants Nippon Kayaku exclusive rights to market and distribute Gelpart (development code # YM670) and to develop additional indications for it in Japan.
- Prograf (development code # FK506) capsules was approved for the new indication of the treatment of rheumatoid arthritis in patients who respond insufficiently to current therapies in Japan.
- Phase-III studies of YM026 for the concomitant treatment of type II diabetes with insulin sensitizers (a new indication) were initiated in Japan.
- VESIcare (development code # YM905) and Vesicare (development code # YM905) were launched in the US and in Europe, respectively.
- Omnic OCAS (development code # YM617) was launched in Europe.
- Mycamine (development code # FK463) was approved and launched in the US.
- Phase-II studies of YM087 for the treatment of acutely decompensated chronic heart failure were terminated in the US and Europe.