R&D Pipeline (May 2009)

1.Global development

(1) Approval

Code No. Generic Name	Product Name (Approval Date)	Classification	Therapeutic Target	Area	Dosage Form	Origin	Remarks
FK506 tacrolimus	Protopic ointment (Feb. 2009)	Immunosuppressant	Atopic dermatitis (Prevention of flares)	Europe	Ointment	In-house	New indication

(2) Filed

Stage in the Most Advanced Territory

Code No. Generic Name	Classification	Therapeutic Target	Area / Phase	Dosage Form	Origin	Remarks
FK506 tacrolimus	Immunosuppressant	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		New formulation
		Ulcerative colitis	Japan Filed (June 2008)	Oral		New indication
		Myasthenia gravis (all)	Japan Filed (Sep. 2008)	Oral		New indication
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		New indication
telavancin	Lipoglycopeptide antibiotic	Complicated skin and skin structure infections (cSSSI)	USA Filed (Dec. 2006) **	Injection	Theravance	
			Europe Phase-III ***			
		Hospital-acquired pneumonia (HAP)	USA Filed (Jan. 2009) Europe Phase-III			
		MRSA infections	Japan Phase-I			

*FK506: Received an approvable letter from the FDA in March 2007
**telavancin: Received an approvable letter from the FDA in October 2007, Received a complete response letter from the FDA in February 2009
***telavancin: The MAA was withdrawn in Europe in October 2008

(2) 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 mirabegron	Beta 3 receptor agonist	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	USA Phase-III Europe Phase-III Japan Phase-III	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-III	Oral	In-house	
		Prophylaxis of thromboembolic complications associated with atrial fibrillation (AF)	Europe Phase-II Japan/Asia Phase-II			
YM443 acotiamide	Acetylcholine esterase inhibitor	Functional dyspepsia	Japan Phase-III USA Phase-II	Oral	Zeria	
solifenacin/ tamsulosin	Co-administration of solifenacin and tamsulosin	Lower urinary tract syndrome associated with benign prostatic hyperplasia (BPH)	Europe Phase-III	Oral	In-house	
YM155	Survivin suppressant	Cancer	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	
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	

(2) 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	
YM060 ramosetron	5-HT3 receptor antagonist	Irritable bowel syndrome (IBS)	Europe Phase-II	Oral	In-house	
YM905 solifenacin	Muscarine M_3 receptor antagonist	Urinary frequency, urinary incontinence or urgency associated with overactive bladder (orally-disintegrating tablet)	Japan Phase-II	Oral	In-house	New formulation
AGS-1C4D4	Antibody (Prostate stem cell antigen)	Pancreatic cancer	USA/Europe Phase-II	Injection	In-house (Agensys)	

2.Local development: Japan

(1) Approval

Code No. Generic Name	Product Name (Approval Date)	Classification	Therapeutic Target	Area	Dosage Form	Origin	Remarks
BIBR277HCT telmisartan/ hydrochlorothiazide	Micombi (Apr. 2009)	Combination drug of angiotensin II receptor blocker / diuretic	Hypertension	Japan	Oral	Boehringer Ingelheim	Combination drug

(2) Filed

Most Advanced Stage

Code No. Generic Name	Classification	Therapeutic Target	Area / Phase	Dosage Form	Origin	Remarks
YM086 (BIBR277) telmisartan	Angiotensin II receptor blocker	Type 2 diabetic nephropathy	Japan Filed (June 2006)	Oral	Boehringer Ingelheim	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			

(3) 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
YM529 minodronate	Bisphosphonate	Osteoporosis (intermittent administration)	Japan Phase-III	Oral	In-house (co-development with Ono)	New formulation
ASP1585 (AMG223)	Non-absorbed, polymer-based phosphate binder	Hyperphosphatemia	Japan Phase-III	Oral	Ilypsa/Amgen	
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	
ASP3550 degarelix	GnRH receptor antagonist	Prostate cancer	Japan Phase-II	Injection	Ferring	

3.Local development: USA

(1) 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	

*Received an approvable letter from the FDA in August 2008

4.Phase-I

Code No. Generic Name	Therapeutic Target	Dosage Form	Origin
ASP0265	Prostate cancer, Endometriosis	Oral	In-house
ASK8007	Rheumatoid arthritis	Injection	IBL Kaketsuken (co-development)
ASP2905	Alzheimer's disease (Dementia), Schizophrenia	Oral	In-house
ASP015K	Suppression of organ rejection in organ transplant	Oral	In-house
AGS-16M18	Cancer	Injection	In-house (Agensys)
AGS-8M4	Cancer	Injection	In-house (Agensys)
ASKP1240	Suppression of organ rejection in organ transplant	Injection	Kyowa Hakko Kirin
ASP3652	Overactive bladder	Oral	In-house
ASP7035	Nocturia	Oral	In-house
ASP0777	Alzheimer's disease (Dementia)	Oral	In-house

5. Projects Discontinued

Code No. Generic Name	Area / Phase	Therapeutic Target	Reason
YM543	Europe Phase- II	Type 2 diabetes	Putting the development of ASP1941 ahead, whose mechanism of action is same as YM543, was decided.
ASP2314	Phase- I	Schizophrenia	Due to strategic considerations with respect to the development for the treatment of schizophrenia, discontinuation of development was decided.
ASP2535	Phase- I	Alzheimer's disease (Dementia), Schizophrenia	Considering the results of Phase-I, discontinuation of development was decided.

Changes from the previous announcement (Financial results announcement on February 2, 2009)

- YM529 (Product name Bonoteo (once daily) in Japan) was launched and deleted from the list.
- YM026 (Product name Starsis in Japan) was launched and deleted from the list.
- YM087 (Product name Vaprisol (Pre-mix bag formulation) in USA) was launched and deleted from the list.
- FK506 ointment (Product name Protopic ointment in Europe) was approved.
- BIBR277HCT(Product name Micombi in Japan) was approved.
- Telavancin (Hospital-acquired pneumonia in USA) was filed.
- YM178 (Urinary frequency, urinary incontinence or urgency associated with overactive bladder in Japan) enters Phase-III.
- YM150 (Prevention of venous thromboembolism (VTE) after major orthopedic surgery in Japan/Asia) enters Phase-III.
- Solifenacin/ tamsulosin (Lower urinary tract syndrome associated with benign prostatic hyperplasia (BPH) in Europe) enters Phase-III.
- ASP1585(AMG223) (Hyperphosphatemia in Japan) enters Phase-III.
- AGS-1C4D4 (Pancreatic cancer in USA/Europe) entered Phase-II.
- ASP7035 (Nocturia) entered Phase-I.
- ASP0777 (Alzheimer’s disease (Dementia)) entered Phase-I.
- Development of ASP543 (Type 2 diabetic, Phase-II in Europe) was discontinued and deleted from the list.
- Development of ASP2314 (Schizophrenia, Phase-I) was discontinued and deleted from the list.
- Development of ASP2535 (Alzheimer’s disease (Dementia), Schizophrenia, Phase-I) was discontinued and deleted from the list.