R&D Pipeline (As of January 2016)

Underlined items indicate for changes from the previous announcement on October 30, 2015.

1. Global Development

(1) Filed

*Compounds with "In-house" in this column include ones discovered by collaborative research. (The same applicable hereafter.)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor*	Remarks
YM905 solifenacin	Muscarine M_3 receptor antagonist	Overactive bladder in pediatric patients of 5-18 years	Europe Filed (Sept. 2015)	Oral	In-house	New indication (pediatric)

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

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
MDV3100 enzalutamide	Androgen receptor inhibitor	Non-metastatic castration-resistant prostate cancer, Prostate cancer in patients with non-metastatic biochemical recurrence	US/Europe/Asia Phase-III	Oral	Medivation	New indication
		Metastatic hormone-sensitive prostate cancer	US/Europe/Japan/Asia Phase-III			New indication
		Breast cancer	US/Europe Phase-II			New indication
		Hepatocellular carcinoma	US/Europe/Asia Phase-II			New indication
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients	US/Europe/Japan Phase-III	Injection	Vical	
		Cytomegalovirus infection or reactivation in solid organ transplant recipients	US/Europe Phase-II			

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

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
YM905 solifenacin	Muscarine M_3 receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	US/Europe Phase-III	Oral	In-house	New indication (pediatric)
EB178 solifenacin/ mirabegron	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	US/Europe/Asia Phase-III	Oral	In-house	
fidaxomicin	Macrocyclic antibiotic	Infectious enteritis (bacterial target: *Clostridium difficile*)	Japan Phase-III	Oral	Merck	
		Clostridium difficile infection in pediatric patients	Europe Phase-III			New indication (pediatric)
ASP015K	JAK inhibitor	Rheumatoid arthritis	Japan/Asia Phase-III US/Europe Phase-II	Oral	In-house	
ASP1517 (FG-4592) roxadustat	HIF stabilizer	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis	Europe Phase-III Japan Phase-II	Oral	FibroGen	
ASP2215 gilteritinib	FLT3/AXL inhibitor	Acute myeloid leukemia	US/Europe/Japan/Asia Phase-III	Oral	In-house	
		Non-small cell lung cancer	US/Japan/Asia Phase-I			
ASP8273	Mutant-selective irreversible EGFR inhibitor	Non-small cell lung cancer	US/Europe/Japan/Asia Phase-III	Oral	In-house	
YM311 (FG-2216)	HIF stabilizer	Renal anemia	Europe Phase-II Japan Phase-I	Oral	FibroGen	

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

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
ASKP1240	Anti-CD40 monoclonal antibody	Prevention of organ transplant rejection	US Phase-II Japan Phase-I	Injection	Kyowa Hakko Kirin	
ASP1707	GnRH antagonist	Endometriosis	Europe/Japan Phase-II	Oral	In-house	
		Prostate cancer	Europe Phase-I			
ASP8232	VAP-1 inhibitor	Diabetic nephropathy	Europe Phase-II	Oral	In-house	
		Diabetic macular edema	US Phase-II			
ASP3662	11beta-HSD1 inhibitor	Painful diabetic peripheral neuropathy	US Phase-II	Oral	In-house	
		Alzheimer's disease	US Phase-I			
CK-2127107	Fast skeletal tropoinin activator	Spinal muscular atrophy	US Phase-II	Oral	Cytokinetics	
		Chronic obstructive pulmonary disease	US Phase-II			
ASP7962	TrkA inhibitior	Osteoarthritis	Europe Phase-II	Oral	In-house	
AGS-16C3F	ADC targeting ENPP3	Renal cell carcinoma (ADC technology)	US/Europe Phase-II	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	

2. Local Development: Japan

(1) Approved

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Licensor	Remarks
AMG 145 evolocumab (gene recombinant)	Repatha (Jan. 2016)	Anti-PCSK9 human monoclonal antibody	Treatment of patients with familial hypercholesterolemia or hypercholesterolemia who have high risk of cardiovascular events and are not adequately controlled by HMG-CoA reductase inhibitors	Japan	Injection	Amgen (co-development with Amgen Astellas)	

(2) Filed

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
ASP7374	Influenza vaccine	Prophylaxis of seasonal influenza	Japan Filed (May 2014)	Injection	UMN Pharma	
ASP1585 (AMG 223) bixalomer	Amine-functional polymer	Hyperphosphatemia in patients not on dialysis with chronic kidney disease	Japan Filed (Mar. 2015)	Oral	Amgen	New indication
		Hyperphosphatemia in patients on dialysis with chronic kidney disease (granule formulation)	Japan Filed (Sept. 2015)	Oral		New formulation

(3) Phase-III / Phase-II

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
FK949E quetiapine	Serotonin / dopamine antagonist	Depressive episode in bipolar disorders	Japan Phase-III	Oral	AstraZeneca	New indication New formulation
ASP3550 degarelix	GnRH antagonist	Prostate cancer (three-month formulation)	Japan Phase-III	Injection	Ferring	New formulation
AMG 785 romosozumab	Anti-Sclerostin monoclonal antibody	Osteoporosis	Japan Phase-III	Injection	Amgen (co-development with Amgen Astellas)	
ASP0456 linaclotide	Guanylate cyclase type-C receptor agonist	Irritable bowel syndrome with constipation	Japan Phase-III	Oral	Ironwood	
		Chronic constipation	Japan Phase-II			
ipragliflozin/ sitagliptin	Fixed dose combination of ipragliflozin and sitagliptin	Type 2 diabetes mellitus	Japan Phase-III	Oral	In-house (co-development with MSD and Kotobuki)	
ASP7373	Influenza vaccine	Prophylaxis of H5N1 influenza	Japan Phase-II	Injection	UMN Pharma	
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 1 diabetes mellitus	Japan Phase-II	Oral	In-house (co-development with Kotobuki)	New indication

3. Phase-I

Code No. Generic Name	Target Disease	Dosage Form	Licensor
ASG-22ME	Cancer (ADC technology)	Injection	In-house (co-development with Seattle Genetics)
ASG-15ME	Cancer (ADC technology)	Injection	In-house (co-development with Seattle Genetics)
ASP5878	Cancer	Oral	In-house
YM178 mirabegron	Neurogenic detrusor overactivity and idiopathic overactive bladder in pediatric patients	Oral	In-house
AGS67E	Cancer (ADC technology)	Injection	In-house (ADC technology in-licensed from Seattle Genetics)
ASP2205	Stress urinary incontinence	Oral	In-house
ASP5094	Rheumatoid arthritis	Injection	In-house
ASP6858	Chronic kidney disease	Oral	In-house
AMG 103 blinatumomab	Acute lymphoblastic leukemia	Injection	Amgen (co-development with Amgen Astellas)
ASP4132	Cancer	Oral	In-house
ASP4345	Cognitive impairment associated with schizophrenia	Oral	In-house
ASP6282	Underactive bladder	Oral	In-house
ASP4070 (JRC2-LAMP-vax)	Pollinosis caused by Japanese red cedar	Injection	Immunomic Therapeutics
ASP0819	Fibromyalgia	Oral	In-house
ASP8062	Fibromyalgia	Oral	In-house
ASP7398	Nocturia	Oral	In-house
ASP6294	Bladder pain syndrome / Interstitial cystitis	Injection	In-house
ASP7266	Severe asthma	Injection	In-house

4. Project Discontinued

Code No. Generic Name	Target Disease	Area / Phase	Reason
isavuconazonium sulfate	Candidemia / Invasive candidiasis	US Phase-III	Decided not to continue the development in candidemia/invasive candidiasis, because the primary endpoint of the overall treatment response at the end of intravenous therapy was not met in the Phase-III study.

5. Other items changed from the previous quarterly announcement on October 30, 2015

-Removed the description of Qutenza (capsaicin patch), for which new indication was approved in Europe in August 2015.