R&D Pipeline (As of July 2016)

Underlined items indicate for changes from the previous announcement on May 11, 2016.

1. Global Development

(1) Regulatory decision

*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	Oral	In-house	Received a notification for end of procedure for the type 2 variation. The indication was not approved but pediatric information was included in the label to enable patent extension of 6 months.

(2) Filed

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
MDV3100 enzalutamide*	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer (Tablet)	Europe Filed (Mar. 2016)	Oral	Medivation	New formulation

* Withdrew the US sNDA in Feb. 2016 for tablet.

(3) Phase-lll / Phase-ll (1/4)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
MDV3100 enzalutamide	Androgen receptor inhibitor	Non-metastatic castration-resistant prostate cancer	US/Europe/Asia Phase-III	Oral	Medivation	New indication
		Prostate cancer in patients with non-metastatic biochemical recurrence	US/Europe/Asia Phase-III			New indication
		Metastatic hormone-sensitive prostate cancer	US/Europe/Japan/Asia Phase-III			New indication
		Triple-negative breast cancer	US/Europe/Japan/Asia Phase-III			New indication
		Breast cancer (ER/PgR positive, HER2 positive)	US/Europe Phase-II			New indication
		Hepatocellular carcinoma	US/Europe/Asia Phase-II			New indication

(3) Phase-Ⅲ / Phase-Ⅱ (2/4)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
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			
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 peficitinib	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-III	Oral	FibroGen	

(3) Phase-lll / Phase-ll (3/4)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
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	
YM178 mirabegron	Beta 3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	Europe Phase-III	Oral	In-house	New indication (pediatric)
YM311 (FG-2216)	HIF stabilizer	Renal anemia	Europe Phase-II Japan Phase-I	Oral	FibroGen	
ASKP1240 bleselumab	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients*	US Phase-II	Injection	Kyowa Hakko Kirin	
ASP1707	GnRH antagonist	Endometriosis	Europe/Japan Phase-II	Oral	In-house	
		Rheumatoid arthritis	Japan Phase-II			
ASP8232	VAP-1 inhibitor	Diabetic nephropathy	Europe Phase-II	Oral	In-house	
		Diabetic macular edema	US Phase-II			

* It was in the Phase-II stage in the US and Phase-I stage in Japan for prevention of organ transplant rejection. We have decided to focus on recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients in future development.

(3) Phase-lll / Phase-ll (4/4)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
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	US/Europe Phase-II	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
RPE cell program	Cell therapy (Retinal pigment epithelium cell)	Dry age-related macular degeneration, Stargardt's macular degeneration	US Phase-II	Injection	In-house (Astellas Institute for Regenerative Medicine)	

2. Local Development: Japan

(1) 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 on dialysis with chronic kidney disease (granule formulation)	Japan Filed (Sept. 2015)	Oral	Amgen	New formulation
ASP0456 linaclotide	Guanylate cyclase-C receptor agonist	Irritable bowel syndrome with constipation	Japan Filed (Feb. 2016)	Oral	Ironwood	

(2) 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 (3-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)	
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)	
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 1 diabetes mellitus	Japan Phase-III	Oral	In-house (co-development with Kotobuki)	New indication
ASP0456 linaclotide	Guanylate cyclase-C receptor agonist	Chronic constipation	Japan Phase-III	Oral	Ironwood	New indication
ASP7373	Influenza vaccine	Prophylaxis of H5N1 influenza	Japan Phase-II	Injection	UMN Pharma	
AMG 103 blinatumomab	Anti-CD19 BiTE	Acute lymphoblastic leukemia	Japan Phase-II	Injection	Amgen (co-development with Amgen Astellas)	

3. Phase-I

Code No. Generic Name	Target Disease	Dosage Form	Licensor
ASG-22ME enfortumab vedotin	Solid tumors, Urothelial cancer	Injection	In-house (co-development with Seattle Genetics)
ASG-15ME	Urothelial cancer	Injection	In-house (co-development with Seattle Genetics)
ASP5878	Cancer	Oral	In-house
AGS67E	Lymphoid Malignancies	Injection	In-house (ADC technology in-licensed from Seattle Genetics)
ASP2205	Stress urinary incontinence	Oral	In-house
ASP5094	Rheumatoid arthritis	Injection	In-house
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
ASP0892	Peanut allergy	Injection	Immunomic Therapeutics
AGS62P1	Acute myeloid leukemia	Injection	In-house (ADC technology, EuCODE license from Ambrx)

4. Other items changed from the previous quarterly announcement on May 11, 2016

-Removed the description for new indication of Kiklin (bixalomer), which was approved in February 2016 in Japan.