R&D Pipeline (As of January 2017)

Underlined items indicate for changes from the previous announcement on October 28, 2016.

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
MDV3100 enzalutamide	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer (Tablet)	Europe Filed (Mar. 2016)	Oral	Pfizer	New formulation
		Castration-resistant prostate cancer (Tablet)	Japan Filed (Sept. 2016)			

(2) Phase-III / Phase-II (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	Pfizer	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/PR positive, HER2 positive)	US/Europe Phase-II			New indication
		Hepatocellular carcinoma	US/Europe/Asia Phase-II			New indication

(2) 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	
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	

(2) Phase-III / Phase-II (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	
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	
CK-2127107	Fast skeletal troponin activator	Spinal muscular atrophy	US Phase-II	Oral	Cytokinetics	
		Chronic obstructive pulmonary disease	US Phase-II			

(2) Phase-III / Phase-II (4/4)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
ASP7962	TrkA inhibitor	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)	
ASP8062	$GABA_B$ receptor positive allosteric modulator	Fibromyalgia	US Phase-II	Oral	In-house	
ASP0819	Calcium^{2+}-activated K^+ channel opener	Fibromyalgia	US Phase-II	Oral	In-house	
IMAB362	Anti-Claudin 18.2 monoclonal antibody	Gastroesophageal adenocarcinoma	Europe Phase-II	Injection	In-house (Ganymed)	
ASG-22ME enfortumab vedotin	ADC targeting nectin-4	Urothelial cancer	US Phase-II	Injection	In-house (co-development with Seattle Genetics)	
ASP3662	11beta-HSD1 inhibitor	Agitation associated with Alzheimer's disease	US Phase-II	Oral	In-house	

2. Local Development: Japan

(1) Approved

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Licensor	Remarks
ASP0456 linaclotide	LINZESS (Dec. 2016)	Guanylate cyclase-C receptor agonist	Irritable bowel syndrome with constipation	Japan	Oral	Ironwood	

(2) Filed

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
FK949E quetiapine	Serotonin / dopamine antagonist	Improvement of depressive symptoms associated with bipolar disorder (Extended-release tablet)	Japan Filed (Aug. 2016)	Oral	AstraZeneca	
AMG 785 romosozumab	Anti-Sclerostin monoclonal antibody	Osteoporosis for those at high risk of fracture	Japan Filed (Dec. 2016)	Injection	Amgen (co-development with Amgen Astellas)	

(3) Phase-III / Phase-II

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
ASP3550 degarelix	GnRH antagonist	Prostate cancer (3-month formulation)	Japan Phase-III	Injection	Ferring	New formulation
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
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-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)
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
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)
ASP1807 (CC8464)	Neuropathic pain	Oral	Chromocell
ASP8302	Underactive bladder	Oral	In-house

4. Discontinued

(1) Filed/Phase II

Code No.	Target Disease	Area / Phase	Reason
ASP7374	Prophylaxis of seasonal influenza	Japan Filed	Excercised the right to terminate the agreement with UMN Pharma. Withdrew the application for marketing approval based on the comprehensive consideration.
ASP7373	Prophylaxis of H5N1 influenza	Japan Phase-II	Excercised the right to terminate the agreement with UMN Pharma.

(2) Phase-I

Code No.	Target Disease
ASP2205	Stress urinary incontinence

(3) Discontinued in a part of indication

Code No. Generic Name	Target Disease	Area / Phase	Reason
ASP2215 gilteritinib	Non-small cell lung cancer	US/Japan/Asia Phase-I	The Phase-I study was terminated due to adverse events in combination therapy.

5. Other items changed from the previous quarterly announcement on October 28, 2016

-Removed the description of Kiklin granules approved in Japan in September 2016.