R&D Pipeline (As of October 2016)

Underlined items indicate for changes from the previous announcement on July 29, 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	Medivation	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	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

(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	
		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	

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

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
CK-2127107	Fast skeletal troponin 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)	
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	

2. Local Development: Japan

(1) Approved

Code No. Generic Name	Product Name (Approval Date)	Classification	Target Disease	Area	Dosage Form	Licensor	Remarks
ASP1585 (AMG 223) bixalomer	Kiklin Granules (Sept. 2016)	Amine-functional polymer	Treatment of hyperphosphatemia in patients with chronic kidney disease (granule formulation)	Japan	Oral	Amgen	New formulation

(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	
ASP0456 linaclotide	Guanylate cyclase-C receptor agonist	Irritable bowel syndrome with constipation	Japan Filed (Feb. 2016)	Oral	Ironwood	
FK949E quetiapine	Serotonin / dopamine antagonist	Improvement of depressive symptoms associated with bipolar disorder (Extended-release tablet)	Japan Filed (Aug. 2016)	Oral	AstraZeneca	

(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
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
ASP3662	Alzheimer's disease	Oral	In-house
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
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) Discontinued in a part of indication

Code No. Generic Name	Target Disease	Area / Phase	Reason
ASP0113 (VCL-CB01)	Cytomegalovirus infection or reactivation in solid organ transplant recipients	US/Europe Phase-II	The Phase-II study did not meet its primary endpoint.
ASP8232	Diabetic macular edema	US Phase-II	The Phase-II study did not meet its primary endpoint.
ASP3662	Painful diabetic peripheral neuropathy	US Phase-II	The Phase-II study was terminated due to futility analysis for efficacy.

5. Other items changed from the previous quarterly announcement on July 29, 2016

-Removed the description of solifenacin for overactive bladder in pediatric patients, for which review was completed in Europe.