R&D Pipeline (As of Jan 2018)

Underlined items indicate changes from the previous announcement on Oct 31, 2017.

Oncology (1/2)

*Compounds with "In-house" in this column include ones discovered by collaborative research.

Code No. Generic Name	Classification	Target Disease	Phase / Area	Dosage Form	Licensor*	Remarks
MDV3100 enzalutamide	Androgen receptor inhibitor	Castration-resistant prostate cancer (Tablet)	Filed (Sep. 2016) / Japan	Oral	Pfizer	New formulation
		Non-metastatic castration-resistant prostate cancer	Filed (Jan. 2018) / US, Europe			New indication
		Prostate cancer in patients with non-metastatic biochemical recurrence	P-III / US, Europe, Asia			New indication
		Metastatic hormone-sensitive prostate cancer	P-III / US, Europe, Japan, Asia			New indication
ASP3550 degarelix	GnRH antagonist	Prostate cancer (3-month formulation)	Filed (Nov. 2017) / Japan	Injection	Ferring	New formulation
AMG 103 blinatumomab	Anti-CD19 BiTE antibody	Acute lymphoblastic leukemia	Filed (Jan. 2018) / Japan	Injection	Amgen (co-development with Amgen Astellas)	
ASP2215 gilteritinib	FLT3/AXL inhibitor	Acute myeloid leukemia	P-III / US, Europe, Japan, Asia	Oral	In-house	
IMAB362	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III / US, Europe, Japan, Asia	Injection	In-house (Ganymed)	
AGS-16C3F	ADC targeting ENPP3	Renal cell carcinoma	P-II / US, Europe	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
ASG-22ME enfortumab vedotin	ADC targeting nectin-4	Urothelial cancer	P-II / US, Europe, Japan, Asia P-I / Japan	Injection	In-house (co-development with Seattle Genetics)	
AGS67E		Lymphoid malignancies	P-I	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
AGS62P1		Acute myeloid leukemia	P-I	Injection	In-house (ADC technology, EuCODE license from Ambrx)	
ASP8374/PTZ-201		Cancer	P-I	Injection	Option agreement with Potenza Therapeutics	

Oncology (2/2)

Updates from the previous announcement (Oct. 2017):
MDV3100 (enzalutamide): Applications for marketing approval for non-metastatic castration resistant prostate cancer in US and EU were submitted in Jan. 2018. Discontinued Phase 2 program for hepatocellular carcinoma because Phase 2 study did not meet the primary endpoint.
ASP3550 (degarelix): Applications for marketing approval for prostate cancer (3-month formulation) in Japan was submitted in Nov. 2017.
AMG103 (blinatumomab): Applications for marketing approval for acute lymphoblastic leukemia in Japan was submitted in Jan. 2018.
IMAB362: Clinical development for gastric and gastroesophageal junction adenocarcinoma has been progressed from Phase 2 to Phase 3.

Urology and Nephrology

*Compounds with "In-house" in this column include ones discovered by collaborative research.

Code No. Generic Name	Classification	Target Disease	Phase / Area	Dosage Form	Licensor*	Remarks
YM905 solifenacin	Muscarine M_3 receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	Filed (Feb. 2017) / US Filed (Apr. 2017) / Europe	Oral	In-house	New indication (pediatric)
EB178 solifenacin/ mirabegron	Combination therapy of solifenacin and mirabegron	Overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	Filed (Jun. 2017) / US	Oral	In-house	
ASP1517 (FG-4592) roxadustat	HIF stabilizer	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis	P-III / Europe P-III / Japan	Oral	FibroGen	
YM178 mirabegron	Beta 3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	P-III / Europe	Oral	In-house	New indication (pediatric)
YM311 (FG-2216)	HIF stabilizer	Renal anemia	P-II / Europe P-I / Japan	Oral	FibroGen	
ASP8232	VAP-1 inhibitor	Diabetic kidney disease	P-II / Europe	Oral	In-house	
ASP6294	Nerve Growth Factor (NGF) neutralization antibody	Bladder pain syndrome / Interstitial cystitis	P-II / Europe	Injection	In-house	
ASP8302	Muscarine M_3 receptor positive allosteric modulator	Underactive bladder	P-II / Europe, Japan	Oral	In-house	
ASP7713		Underactive bladder	P-I	Oral	In-house	
MA-0217		Acute kidney injury	P-I	Oral	In-house (Mitobridge)	

Update from the previous announcement (Oct. 2017):
ASP8302: Clinical development for underactive bladder has been progressed from Phase 1 to Phase 2.
ASP7398: Discontinued Phase 1 program for nocturia.
ASP6282: Discontinued Phase 1 program for underactive bladder.
MA-0217: Initiated clinical development for acute kidney injury.

Immunology and Neuroscience

*Compounds with "In-house" in this column include ones discovered by collaborative research.

Code No. Generic Name	Classification	Target Disease	Phase / Area	Dosage Form	Licensor*	Remarks
FK506 tacrolimus	Immunosuppressant	Prevention of rejection after organ transplantation (Granule formulation in pediatric use)	Filed (Jul. 2017) / US	Oral	In-house	New formulation
ASP015K peficitinib	JAK inhibitor	Rheumatoid arthritis	P-III / Japan, Asia P-II / US, Europe	Oral	In-house	
ASKP1240 bleselumab	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	P-II / US	Injection	Kyowa Hakko Kirin	
ASP1707	GnRH antagonist	Rheumatoid arthritis	P-II / Japan	Oral	In-house	
ASP8062	$GABA_B$ receptor positive allosteric modulator	Fibromyalgia	P-II / US	Oral	In-house	
ASP0819	$Calcium^{2+}$-activated K^+ channel opener	Fibromyalgia	P-II / US	Oral	In-house	
ASP4070 (JRC2-LAMP-vax)	DNA vaccine for Japanese red cedar	Pollinosis caused by Japanese red cedar	P-II / Japan	Injection	Immunomic Therapeutics	
ASP5094	Anti-alpha-9 integrin monoclonal antibody	Rheumatoid arthritis	P-II / Japan	Injection	In-house	
ASP4345	Dopamine D_1 receptor positive allosteric modulator	Cognitive impairment associated with schizophrenia	P-II / US	Oral	In-house	
ASP0892		Peanut allergy	P-I	Injection	Immunomic Therapeutics	
ASP1807 (CC8464)		Neuropathic pain	P-I	Oral	Chromocell	
ASP6981		Cognitive impairment associated with schizophrenia	P-I	Oral	In-house	

Update from the previous announcement (Oct. 2017):
ASP7962: Discontinued Phase 2 program for osteoarthritis because Phase 2 study did not meet its primary endpoint.
ASP4345: Clinical development for cognitive impairment associated with schizophrenia has been progressed from Phase 1 to Phase 2.

Others

*Compounds with "In-house" in this column include ones discovered by collaborative research.

Code No. Generic Name	Classification	Target Disease	Phase / Area	Dosage Form	Licensor*	Remarks
AMG 785 romosozumab	Anti-Sclerostin monoclonal antibody	Osteoporosis for those at high risk of fracture	Filed (Dec. 2016) / Japan	Injection	Amgen (co-development with Amgen Astellas)	
ipragliflozin/ sitagliptin	Fixed dose combination of ipragliflozin and sitagliptin	Type 2 diabetes	Filed (May 2017) / Japan	Oral	In-house (co-development with MSD and Kotobuki)	
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 1 diabetes	Filed (Jan. 2018) / Japan	Oral	In-house (co-development with Kotobuki)	New indication
ASP0456 linaclotide	Guanylate cyclase-C receptor agonist	Chronic constipation	Filed (Sep. 2017) / Japan	Oral	Ironwood	New indication
fidaxomicin	Macrocyclic antibiotic	Infectious enteritis (bacterial target: *Clostridium difficile*)	Filed (Jul. 2017) / Japan	Oral	Merck	
		Clostridium difficile infection in pediatric patients	P-III / Europe			New indication (pediatric)
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients	P-III / US, Europe, Japan	Injection	Vical	
ESN364 fezolinetant	NK3 receptor antagonist	Menopause-related vasomotor symptoms	P-II / US	Oral	In-house (Ogeda)	
ASP1707	GnRH antagonist	Endometriosis	P-II / Europe, Japan	Oral	In-house	
CK-2127107 reldesemtiv	Fast skeletal troponin activator	Spinal muscular atrophy	P-II / US	Oral	Cytokinetics	
		Chronic obstructive pulmonary disease	P-II / US			
		Amyotrophic lateral sclerosis	P-II / US			
ASP7317	Cell therapy (Retinal pigment epithelium cell)	Dry age-related macular degeneration, Stargardt's macular degeneration	P-II / US	Injection	In-house (Astellas Institute for Regenerative Medicine)	
MA-0211		Duchenne muscular dystrophy	P-I	Oral	In-house (Mitobridge)	

Updates from the previous announcement (Oct. 2017):
ASP1941(ipragliflozin): Application for market approval for Type 1 diabetes was submitted in Japan in Jan. 2018.