R&D Pipeline (As of July 2017)

Underlined items indicate changes from the previous announcement on April 27, 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	Metastatic castration-resistant prostate cancer (Tablet)	Filed (Mar. 2016) / Europe	Oral	Pfizer	New formulation
		Castration-resistant prostate cancer (Tablet)	Filed (Sept. 2016) / Japan			New formulation
		Non-metastatic castration-resistant prostate cancer	P-III / US, Europe, Asia			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
		Hepatocellular carcinoma	P-II / US, Europe, Asia			New indication
ASP2215 gilteritinib	FLT3/AXL inhibitor	Acute myeloid leukemia	P-III / US, Europe, Japan, Asia	Oral	In-house	
ASP3550 degarelix	GnRH antagonist	Prostate cancer (3-month formulation)	P-III / Japan	Injection	Ferring	New formulation
AGS-16C3F	ADC targeting ENPP3	Renal cell carcinoma	P-II / US, Europe	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
IMAB362	Anti-Claudin 18.2 monoclonal antibody	Gastroesophageal adenocarcinoma	P-II / Europe	Injection	In-house (Ganymed)	
ASG-22ME enfortumab vedotin	ADC targeting nectin-4	Urothelial cancer	P-II / US P-I / Japan	Injection	In-house (co-development with Seattle Genetics)	
AMG 103 blinatumomab	Anti-CD19 BiTE antibody	Acute lymphoblastic leukemia	P-II / Japan	Injection	Amgen (co-development with Amgen Astellas)	
ASG-15ME		Urothelial cancer	P-I	Injection	In-house (co-development with Seattle Genetics)	

Oncology (2/2)

*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
ASP4132		Cancer	P-I	Oral	In-house	
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)	

Updates from the previous announcement (Apr. 2017):

MDV3100 (enzalutamide): Discontinued program for breast cancer (Phase III : Triple negative, Phase II : ER/PR positive, HER2 positive) due to the comprehensive assessment based on discussion with Pfizer including competitive landscape change, need for further diagnostic development and new Phase II data.

ASP8273 (naquotinib): Discontinued Phase III program for non-smal cell lung cancer due to the comprehensive assessment of patient’s benefit and risks following the independent data monitoring committee's recommendation.

ASP5878: Discontinued Phase I program for cancer.

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 nephropathy	P-II / Europe	Oral	In-house	
ASP6294	Nerve Growth Factor (NGF) neutralization antibody	Bladder pain syndrome / Interstitial cystitis	P-II / Europe	Injection	In-house	
ASP6282		Underactive bladder	P-I	Oral	In-house	
ASP7398		Nocturia	P-I	Oral	In-house	
ASP8302		Underactive bladder	P-I	Oral	In-house	
ASP7713		Underactive bladder	P-I	Oral	In-house	

Update from the previous announcement (Apr. 2017):
EB178 (solifenacin/mirabegron): Filed application for combination use of solifenacin and mirabegron in US in June 2017.

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
FK949E quetiapine	Serotonin / dopamine antagonist	Improvement of depressive symptoms associated with bipolar disorder (Extended-release tablet)	Approved (Jul. 2017) / Japan	Oral	AstraZeneca	
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	
ASP7962	TrkA inhibitor	Osteoarthritis	P-II / Europe	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		Cognitive impairment associated with schizophrenia	P-I	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	

Updates from the previous announcement (Apr. 2017):
FK949E (quetiapine): Approved for improvement of depressive symptoms associated with bipolar disorder (extended-release tablet) in US in July 2017.
FK506 (tacrolimus): Filed application for prevention of rejection after organ transplantation (granule formulation in pediatric use) in US in July 2017.
ASP3662: Discontinued Phass II program for agitation associated with Alzheimer's disease due to the comprehensive consideration including strategic prioritization.
ASP5094: Progressed clinical development for rheumatoid arthritis from Phase I to Phase II.
ASP6981: Initiated clinical development for cognitive impairment associated with schizophrenia.
ASP7266: Discontinued Phase I program for severe asthma.

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	P-III / Japan	Oral	In-house (co-development with Kotobuki)	New indication
fidaxomicin	Macrocyclic antibiotic	Infectious enteritis (bacterial target: *Clostridium difficile*)	P-III / Japan	Oral	Merck	
		Clostridium difficile infection in pediatric patients	P-III / Europe			New indication (pediatric)
ASP0456 linaclotide	Guanylate cyclase-C receptor agonist	Chronic constipation	P-III / Japan	Oral	Ironwood	New indication
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	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 RPE cell program	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	Option agreement with Mitobridge	

Updates from the previous announcement (Apr. 2017):
ipragliflozin/sitagliptin: Filed application for fixed dose combination of ipragliflozin and sitagliptin in May 2017.
ESN364 (fezolinetant): Added to the pipeline list per completion of acquisition.
MA-0211: Initiated clinical development for Duchenne muscular dystrophy.