

R&D Pipeline (As of April 2017)

Underlined items indicate changes from the previous announcement on January 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	Licensors*	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
		Triple-negative breast cancer	P-III / US, Europe, Japan, Asia			New indication
		Breast cancer (ER/PR positive, HER2 positive)	P-II / US, Europe			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	
ASP8273 <u>naquotinib</u>	Mutant-selective irreversible EGFR inhibitor	Non-small cell lung cancer	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 <u>P-I / Japan</u>	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)	

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	Licensors*	Remarks
ASG-15ME		Urothelial cancer	P-I	Injection	In-house (co-development with Seattle Genetics)	
ASP5878		Cancer	P-I	Oral	In-house	
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)	

Update from the previous announcement (Jan. 2017):

ASG-22ME (enfortumab vedotin): Clinical development for urothelial cancer has been initiated in Japan.

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	<u>Filed (Feb. 2017) / US</u> <u>Filed (Apr. 2017) / Europe</u>	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	P-III / US, Europe, Asia	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	<u>Nerve Growth Factor (NGF) neutralization antibody</u>	Bladder pain syndrome / Interstitial cystitis	<u>P-II / Europe</u>	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	
<u>ASP7713</u>		<u>Underactive bladder</u>	<u>P-I</u>	<u>Oral</u>	<u>In-house</u>	

Update from the previous announcement (Jan. 2017):

YM905 (solifenacin): Filed for neurogenic detrusor overactivity in pediatric patients in US and Europe.

ASP6294: Clinical development for bladder pain syndrome/interstitial cystitis has been progressed from Phase 1 to Phase 2.

ASP7713: Clinical development for underactive bladder has been initiated.

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)	Filed (Aug. 2016) / Japan	Oral	AstraZeneca	
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients	P-III / US, Europe, Japan	Injection	Vical	
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	
ASP3662	11beta-HSD1 inhibitor	Agitation associated with Alzheimer's disease	P-II / US	Oral	In-house	
ASP4070 (JRC2-LAMP-vax)	<u>DNA vaccine for Japanese red cedar</u>	Pollinosis caused by Japanese red cedar	<u>P-II / Japan</u>	Injection	Immunomic Therapeutics	
ASP5094		Rheumatoid arthritis	P-I	Injection	In-house	
ASP4345		Cognitive impairment associated with schizophrenia	P-I	Oral	In-house	
ASP7266		Severe asthma	P-I	Injection	In-house	
ASP0892		Peanut allergy	P-I	Injection	Immunomic Therapeutics	
ASP1807 (CC8464)		Neuropathic pain	P-I	Oral	Chromocell	

Update from the previous announcement (Jan. 2017):

ASP4070 (JRC2-LAMP-vax): Clinical development for pollinosis caused by Japanese red cedar 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)	
fidaxomicin	Macrocyclic antibiotic	Infectious enteritis (bacterial target: <i>Clostridium difficile</i>)	P-III / Japan	Oral	Merck	New indication (pediatric)
		<i>Clostridium difficile</i> infection in pediatric patients	P-III / Europe			
ipragliflozin/ sitagliptin	Fixed dose combination of ipragliflozin and sitagliptin	Type 2 diabetes mellitus	P-III / Japan	Oral	In-house (co-development with MSD and Kotobuki)	
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 1 diabetes mellitus	P-III / Japan	Oral	In-house (co-development with Kotobuki)	New indication
ASP0456 linaclotide	Guanylate cyclase-C receptor agonist	Chronic constipation	P-III / Japan	Oral	Ironwood	New indication
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			
		<u>Amyotrophic lateral sclerosis</u>	<u>P-II / US</u>			
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)	

Update from the previous announcement (Jan. 2017):

CK-2127107: Clinical development for amyotrophic lateral sclerosis has been initiated.

ASP0456 (linaclotide): LINZESS was launched in Japan in Mar. 2017 and the description for irritable bowel syndrome with constipation (IBS-C) has been removed.