

R&D Pipeline (As of Apr 2018)

Underlined items indicate changes from the previous announcement on Jan 31, 2018.

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)	<u>Approved (Feb. 2018) / Japan</u>	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	Relapsed or refractory acute myeloid leukemia	<u>Filed (Mar. 2018) / US, Japan</u>	Oral	In-house	
		Post-chemo maintenance acute myeloid leukemia	P-III / US, Europe, Japan, Asia			
		Post-HSCT maintenance acute myeloid leukemia	P-III / US, Europe, Japan, Asia			
		Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	P-II/III / US, Europe, Japan, Asia			
		Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	P-I / US, Japan			
IMAB362 zolbetuximab	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)	

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Oncology (2/2)

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Code No. Generic Name	Classification	Target Disease	Phase / Area	Dosage Form	Licensor*	Remarks
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	

Updates from the previous announcement (Jan. 2018):

MDV3100 (enzalutamide): Approval of the tablet formulation for CRPC obtained in Japan in Feb 2018.

ASP2215 (gilteritinib): Applications of market approval for FLT 3 mutation-positive relapsed or refractory acute myeloid leukemia were submitted in Japan and US in Mar 2018.

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	Approved (Feb. 2018) / Europe Filed (Feb. 2017) / US	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	Injection	In-house (Mitobridge)	

Update from the previous announcement (Jan. 2018):

YM905 (solifenacin): Approval for neurogenic detrusor overactivity in pediatric patients obtained in EU in Feb 2018.

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	Licensors*	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	
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 (Jan. 2018):

ASP1707: Discontinued phase 2 program for rheumatoid arthritis because phase 2 study did not meet its primary endpoint.

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	Licensors*	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	<u>Approved (Mar 2018) / Japan</u>	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: <i>Clostridium difficile</i>)	Filed (Jul. 2017) / Japan	Oral	Merck	New indication (pediatric)
		<i>Clostridium difficile</i> infection in pediatric patients	P-III / Europe			
ESN364 fezolinetant	NK3 receptor antagonist	Menopause-related vasomotor symptoms	P-II / US	Oral	In-house (Ogeda)	
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)	

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Updates from the previous announcement (Jan. 2018):

ipragliflozin/sitagliptin: Approval for the fixed dose combination of ipragliflozin and sitagliptin for Type 2 diabetes obtained in Japan in Mar 2018.

ASP0113: Discontinued the phase 3 program for cytomegalovirus reactivation in hematopoietic cell transplant recipients because phase 3 study did not meet its primary endpoint.

ASP1707: Discontinued the phase 2 program for endometriosis due to the comprehensive consideration including strategic prioritization.