

R&D Pipeline (As of Oct 2018)

Underlined items indicate changes from the previous announcement on July 27, 2018.

Oncology (1/2)

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

Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensors*	Focus Area approach
enzalutamide MDV3100 (XTANDI®)	Androgen receptor inhibitor	Non-metastatic castration-resistant prostate cancer	<u>Approved (Oct. 2018) / Europe</u>	Oral	Pfizer	
		Non-metastatic hormone-sensitive prostate cancer	P-III / US, Europe, Asia			
		Metastatic hormone-sensitive prostate cancer	P-III / US, Europe, Japan, Asia			
blinatumomab AMG 103 (BLINCYTO®)	Anti-CD19 BiTE antibody	<u>Relapsed or refractory B-cell acute lymphoblastic leukemia</u>	<u>Approved (Sep. 2018) / Japan</u>	Injection	Amgen (co-development with Amgen Astellas)	
gilteritinib ASP2215	FLT3/AXL inhibitor	Relapsed or refractory acute myeloid leukemia	<u>Approved (Sep. 2018) / Japan</u> Filed (Mar. 2018) / US P-III / Europe, Asia	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			
degarelix ASP3550 (GONAX®)	GnRH antagonist	Prostate cancer (3-month formulation)	Filed (Nov. 2017) / Japan	Injection	Ferring	
zolbetuximab IMAB362	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III / US, Europe, Japan, Asia	Injection	In-house (Ganymed)	
enfortumab vedotin ASG-22ME	ADC targeting nectin-4	Urothelial cancer	P-III / US, Europe, Japan, Asia	Injection	In-house (co-development with Seattle Genetics)	
AGS-16C3F	ADC targeting ENPP3	Renal cell carcinoma	P-II / US, Europe	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
<u>ASP1650</u>	<u>Anti-Claudin 6 monoclonal antibody</u>	<u>Testicular Cancer</u>	<u>P-II / US</u>	<u>Injection</u>	<u>In-house (Ganymed)</u>	

Oncology (2/2)

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Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensor*	Focus Area approach
<u>ASP1235/AGS62P1</u>		Acute myeloid leukemia	P-I	Injection	In-house (ADC technology, EuCODE license from Ambrx)	
<u>ASP8374/PTZ-201</u>		Cancer	P-I	Injection	Option agreement with Potenza Therapeutics	Biology: Cancer Immunology
<u>ASP1948/PTZ-329</u>		Cancer	P-I	Injection	Option agreement with Potenza Therapeutics	Biology: Cancer Immunology
<u>ASP1951/PTZ-522</u>		<u>Cancer</u>	<u>P-I</u>	<u>Injection</u>	<u>Option agreement with Potenza Therapeutics</u>	<u>Biology: Cancer Immunology</u>

Updates from the previous announcement (Jul. 2018):

enzalutamide (MDV3100): Approved in Europe for high-risk non-metastatic castration-resistant prostate cancer in Oct 2018. Removed the previous description of approval in US.

blinatumomab (AMG 103): Approved in Japan for relapsed or refractory B-cell acute lymphoblastic leukemia in Sep 2018.

gilteritinib (ASP2215): Approved in Japan for FLT3 mutation-positive relapsed or refractory acute myeloid leukemia in Sep 2018.

ASP1650: Added a Phase 2 program for testicular cancer.

ASP1951/PTZ-522: Initiated clinical development for cancer.

AGS67E: Discontinued Phase 1 program for lymphoid malignancies.

Immunology, Muscle disease and Ophthalmology

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Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensors*	Focus Area approach
peficitinib ASP015K	JAK inhibitor	Rheumatoid arthritis	Filed (May 2018) / Japan	Oral	In-house	
bleselumab ASKP1240	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	P-II / US	Injection	Kyowa Hakko Kirin	
ASP4070/ JRC2-LAMP-vax	DNA vaccine for Japanese red cedar	Pollinosis caused by Japanese red cedar	P-II / Japan	Injection	Immunomic Therapeutics	Modality/Technology: LAMP-vax technology
ASP5094	Anti-alpha-9 integrin monoclonal antibody	Rheumatoid arthritis	P-II / Japan	Injection	In-house	
reldesemtiv CK-2127107	Fast skeletal troponin activator	Spinal muscular atrophy	P-II / US	Oral	Cytokinetics	Biology: Molecular motor
		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)	Modality/Technology: Cell therapy
MA-0211		Duchenne muscular dystrophy	P-I	Oral	In-house (Mitobridge)	Biology: Mitochondria
ASP0892		Peanut allergy	P-I	Injection	Immunomic Therapeutics	Modality/Technology: LAMP-vax technology

Update from the previous announcement (Jul. 2018):

tacrolimus (FK506): Removed the description of approval in US for granule formulation in pediatric use (prevention of rejection after organ transplantation) in May 2018.

Urology and Nephrology

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Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensor*	Focus Area Approach
solifenacin YM905	Muscarine M ₃ receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	Filed (Feb. 2017) / US	Oral	In-house	
roxadustat ASP1517/FG-4592	HIF stabilizer	Anemia associated with chronic kidney disease in patients on dialysis	Filed (Sep. 2018) / Japan P-III / Europe	Oral	FibroGen	
		Anemia associated with chronic kidney disease in patients not on dialysis	P-III / Europe P-III / Japan			
mirabegron YM178	Beta 3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	P-III / 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)	Biology: Mitochondria

Update from the previous announcement (Jul. 2018):

solifenacin/mirabegron (EB178): Removed the description of approval in US for overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency in Apr 2018.

roxadustat (ASP1517/FG-4592): Filed in Japan for anemia associated with chronic kidney disease in patients on dialysis in Sep 2018.

YM311/FG-2216: Deleted the program for renal anemia from the pipeline list.

Others

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Generic Name Code No. (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensors*	Focus Area approach
linaclotide ASP0456 (LINZESS®)	Guanylate cyclase-C receptor agonist	Chronic constipation	<u>Approved (Aug. 2018) / Japan</u>	Oral	Ironwood	
romosozumab AMG 785	Anti-Sclerostin monoclonal antibody	Osteoporosis for those at high risk of fracture	Filed (Dec. 2016) / Japan	Injection	Amgen (co-development with Amgen Astellas)	
ipragliflozin ASP1941 (Suglat®)	SGLT2 inhibitor	Type 1 diabetes	Filed (Jan. 2018) / Japan	Oral	In-house (co-development with Kotobuki)	
evolocumab AMG 145 (Repatha®)	Anti-PCSK-9 monoclonal antibody	<u>Statin intolerant hypercholesterolemia</u>	<u>Filed (Aug. 2018) / Japan</u>	Injection	Amgen (co-development with Amgen Astellas)	
fidaxomicin	Macrocyclic antibiotic	<i>Clostridium difficile</i> infection in pediatric patients	P-III / Europe	Oral	Merck	
fezolinetant ESN364	NK3 receptor antagonist	Menopause-related vasomotor symptoms	P-II / US P-I / Japan	Oral	In-house (Ogeda)	
ASP0819	Calcium ²⁺ -activated K ⁺ channel opener	Fibromyalgia	P-II / US	Oral	In-house	
ASP4345	Dopamine D ₁ receptor positive allosteric modulator	Cognitive impairment associated with schizophrenia	P-II / US	Oral	In-house	
isavuconazole ASP9766	Azole antifungal	<u>Invasive aspergillosis and mucormycosis in pediatric patients</u>	<u>P-II / US</u>	Injection	Basilea	
ASP1807/CC8464		Neuropathic pain	P-I	Oral	Chromocell	
MucoRice-CTB		Prophylaxis of diarrhea caused by <i>Vibrio cholerae</i>	P-I	Oral	The Institute of Medical Science, the University of Tokyo	

Updates from the previous announcement (Jul. 2018):

fidaxomicin: Removed the description of approval in Japan for infectious enteritis (bacterial target: *Clostridium difficile*) in Jul 2018.

linaclotide (ASP0456): Approved in Japan for chronic constipation in Aug 2018.

evolocumab (AMG 145): Filed in Japan for statin intolerant hypercholesterolemia in Aug 2018.

isavuconazole (ASP9766): Added a Phase 2 program for invasive aspergillosis and mucormycosis in pediatric patients.

ASP6981: Discontinued Phase 1 program for cognitive impairment associated with schizophrenia.