

## R&D Pipeline (As of Jul 2018)

Underlined items indicate changes from the previous announcement on Apr 26, 2018.

### Oncology (1/2)

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

Code No. Generic Name (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensors*	Focus Area approach
MDV3100 enzalutamide (XTANDI®)	Androgen receptor inhibitor	Non-metastatic castration-resistant prostate cancer	<u>Approved (Jul. 2018) / US</u> Filed (Jan. 2018) / Europe	Oral	Pfizer	
		Non-metastatic hormone-sensitive prostate cancer	P-III / US, Europe, Asia			
		Metastatic hormone-sensitive prostate cancer	P-III / US, Europe, Japan, Asia			
ASP3550 degarelix (GONAX®)	GnRH antagonist	Prostate cancer (3-month formulation)	Filed (Nov. 2017) / Japan	Injection	Ferring	
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	Filed (Mar. 2018) / US, Japan 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			
IMAB362 zolbetuximab	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III / US, Europe, Japan, Asia	Injection	In-house (Ganymed)	
ASG-22ME enfortumab vedotin	ADC targeting nectin-4	Urothelial cancer	<u>P-III / US, Europe, Japan, Asia</u>	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)	
AGS67E		Lymphoid malignancies	P-I	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	

**Oncology (2/2)**

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

Code No. Generic Name (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensor*	Focus Area approach
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	<u>Biology:</u> <u>Cancer Immunology</u>
<u>ASP1948/PTZ-329</u>		<u>Cancer</u>	<u>P-I</u>	<u>Injection</u>	<u>Option agreement</u> <u>with Potenza</u> <u>Therapeutics</u>	<u>Biology:</u> <u>Cancer Immunology</u>

**Updates from the previous announcement (Apr. 2018):**

**MDV3100 (enzalutamide):** Approved in US for non-metastatic castration-resistant prostate cancer in Jul 2018.

**ASP1948/PTZ-329:** Initiated clinical development for cancer.

## Immunology, Muscle disease and Ophthalmology

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

Code No. Generic Name (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensor*	Focus Area approach
<b>FK506</b> tacrolimus	Immunosuppressant	Prevention of rejection after organ transplantation (Granule formulation in pediatric use)	<u>Approved (May 2018) / US</u>	Oral	In-house	
<b>ASP015K</b> peficitinib	JAK inhibitor	Rheumatoid arthritis	<u>Filed (May 2018) / Japan</u>	Oral	In-house	
<b>ASKP1240</b> bleseelumab	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	P-II / US	Injection	Kyowa Hakko Kirin	
<b>ASP4070/ JRC2-LAMP-vax</b>	DNA vaccine for Japanese red cedar	Pollinosis caused by Japanese red cedar	P-II / Japan	Injection	Immunomic Therapeutics	<u>Modality/Technology: LAMP-vax technology</u>
<b>ASP5094</b>	Anti-alpha-9 integrin monoclonal antibody	Rheumatoid arthritis	P-II / Japan	Injection	In-house	
<b>CK-2127107</b> reldesemtiv	Fast skeletal troponin activator	Spinal muscular atrophy	P-II / US	Oral	Cytokinetics	<u>Biology: Molecular motor</u>
		Chronic obstructive pulmonary disease	P-II / US			
		Amyotrophic lateral sclerosis	P-II / US			
<b>ASP7317</b>	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)	<u>Modality/Technology: Cell therapy</u>
<b>MA-0211</b>		Duchenne muscular dystrophy	P-I	Oral	In-house (Mitobridge)	<u>Biology: Mitochondria</u>
<b>ASP0892</b>		Peanut allergy	P-I	Injection	Immunomic Therapeutics	<u>Modality/Technology: LAMP-vax technology</u>

### Update from the previous announcement (Apr. 2018):

**FK506 (tacrolimus):** Approved in US for prevention of rejection after organ transplantation (granule formulation in pediatric use) in May 2018.

**ASP015K (peficitinib):** Filed in Japan for rheumatoid arthritis in May 2018.

## Urology and Nephrology

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

Code No. Generic Name (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensors*	Focus Area Approach
<b>EB178</b> solifenacin/ mirabegron	Combination therapy of solifenacin and mirabegron	Overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency	<u>Approved (Apr. 2018) / US</u>	Oral	In-house	
<b>YM905</b> solifenacin	Muscarine M <sub>3</sub> receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	Filed (Feb. 2017) / US	Oral	In-house	
<b>ASP1517/FG-4592</b> roxadustat	HIF stabilizer	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis	P-III / Europe P-II / Japan	Oral	FibroGen	
<b>YM178</b> mirabegron	Beta 3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	P-III / Europe	Oral	In-house	
<b>YM311/FG-2216</b>	HIF stabilizer	Renal anemia	P-II / Europe P-I / Japan	Oral	FibroGen	
<b>ASP6294</b>	Nerve Growth Factor (NGF) neutralization antibody	Bladder pain syndrome / Interstitial cystitis	P-II / Europe	Injection	In-house	
<b>ASP8302</b>	Muscarine M <sub>3</sub> receptor positive allosteric modulator	Underactive bladder	P-II / Europe, Japan	Oral	In-house	
<b>ASP7713</b>		Underactive bladder	P-I	Oral	In-house	
<b>MA-0217</b>		Acute kidney injury	P-I	Injection	In-house (Mitobridge)	<u>Biology: Mitochondria</u>

### Update from the previous announcement (Apr. 2018):

**EB178 (solifenacin/mirabegron):** Approved in US for the combination use of solifenacin and mirabegron in over active bladder patients obtained in Apr 2018.

**ASP8232:** Discontinued Phase 2 program for diabetic kidney disease due to strategic prioritization.

## Others

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

Code No. Generic Name (Brand Name)	Classification	Target Disease	Phase / Area	Dosage Form	Licensors*	Focus Area approach
fidaxomicin	Macrocyclic antibiotic	Infectious enteritis (bacterial target: <i>Clostridium difficile</i> )	Approved (Jul. 2018) / Japan	Oral	Merck	
		<i>Clostridium difficile</i> infection in pediatric patients	P-III / Europe			
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)	
ASP1941 ipragliflozin (Suglat®)	SGLT2 inhibitor	Type 1 diabetes	Filed (Jan. 2018) / Japan	Oral	In-house (co-development with Kotobuki)	
ASP0456 linaclotide (LINZESS®)	Guanylate cyclase-C receptor agonist	Chronic constipation	Filed (Sep. 2017) / Japan	Oral	Ironwood	
ESN364 fezolinetant	NK3 receptor antagonist	Menopause-related vasomotor symptoms	P-II / US P-I / Japan	Oral	In-house (Ogeda)	
ASP0819	Calcium <sup>2+</sup> -activated K <sup>+</sup> channel opener	Fibromyalgia	P-II / US	Oral	In-house	
ASP4345	Dopamine D <sub>1</sub> receptor positive allosteric modulator	Cognitive impairment associated with schizophrenia	P-II / US	Oral	In-house	
ASP1807/CC8464		Neuropathic pain	P-I	Oral	Chromocell	
ASP6981		Cognitive impairment associated with schizophrenia	P-I	Oral	In-house	
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 (Apr. 2018):

**fidaxomicin (Dafclir®):** Approved in Japan for infectious enteritis (bacterial target: *Clostridium difficile*) in Jul 2018.

**ASP8062:** Discontinued Phase 2 program for fibromyalgia because Phase 2 study did not meet its primary endpoint.

**MucoRice-CTB:** Initiated clinical development for prophylaxis of diarrhea caused by *Vibrio cholerae*.