

## R&D Pipeline

The list shows the development status in the target diseases for which we aim to obtain approval in Japan, the United States, Europe and/or China.

As of Oct 2019

Underlined items indicate changes from the previous announcement on Jul 30, 2019.

### Key post-POC projects and projects to maximize their VALUE (1/2)

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Dosage Form	Licensor **	Remarks
Oncology	enzalutamide MDV3100 (XTANDI®)	Small molecule	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer	China Filed (Mar 2018)	Oral	Pfizer	
				<u>Non-metastatic castration-resistant prostate cancer</u>	<u>China Filed (Oct 2019)</u>			
				Metastatic hormone-sensitive prostate cancer	US Filed (Jun 2019) Europe Filed (Jul 2019) <u>Japan Filed (Jul 2019)</u> <u>China P-III</u>			
				Non-metastatic hormone-sensitive prostate cancer	P-III			
	gilteritinib ASP2215 (XOSPATA®)	Small molecule	FLT3 inhibitor	Relapsed or refractory acute myeloid leukemia	<u>Europe Approved (Oct 2019)</u> China P-III	Oral	In-house	
				Post-chemotherapy maintenance acute myeloid leukemia	P-III			
				Post-hematopoietic stem cell transplant maintenance acute myeloid leukemia	P-III			
				Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	P-III			
				Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	P-III			
	enfortumab vedotin ASG-22ME	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Locally advanced or metastatic urothelial cancer in patients who have received prior treatment with a PD-1/PD-L1 inhibitor and platinum-containing chemotherapy	US Filed (Jul 2019)	Injection	In-house [Co-development with Seattle Genetics]	
				Urothelial cancer	P-III			
	zolibetuximab IMAB362	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III	Injection	In-house (Ganymed)	
Pancreatic adenocarcinoma				P-II				

**Key post-POC projects and projects to maximize their VALUE (2/2)**

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Dosage Form	Licensors **	Remarks
Urology and Nephrology	roxadustat ASP1517/FG-4592	Small molecule	HIF-PH inhibitor	Anemia associated with chronic kidney disease in patients on dialysis	Japan Approved (Sep 2019) Europe P-III	Oral	FibroGen	Astellas has rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.
				Anemia associated with chronic kidney disease in patients not on dialysis	Japan P-III Europe P-III			
				Chemotherapy-induced anemia	P-II			
Others	fezolinetant ESN364	Small molecule	NK3 receptor antagonist	Menopause-related vasomotor symptoms	P-III	Oral	In-house (Ogeda)	

\* Compounds are developed globally unless noted. The list shows the most advanced stage if the stages are different depending on the region. The list specifies the area if the compound is developed in limited areas.

"Filed" includes submission of application.

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

**Updates from the previous announcement (Jul 2019):**

**gilteritinib (ASP2215):** Approved in Europe for FLT3 mutation positive relapsed or refractory acute myeloid leukemia in Oct 2019.

**roxadustat (ASP1517/FG-4592):** Approved in Japan for anemia associated with chronic kidney disease in patients on dialysis in Sep 2019.

**enzalutamide (MDV3100):** Filed in Japan for metastatic hormone-sensitive prostate cancer in Jul 2019. Submitted in China for non-metastatic castration-resistant prostate cancer in Oct 2019. Phase 3 program in China for metastatic hormone-sensitive prostate cancer has been initiated.

Projects with Focus Area approach

Target (Biology)	Generic Name Code No. (Brand Name)	Modality / Technology	Therapeutic Area	Classification	Target Disease	Phase *	Dosage Form	Licensor **	Remarks
Immunology	ASP8374/PTZ-201	Antibody	Oncology	Anti-TIGIT antibody	Cancer	P-I	Injection	In-house (Potenza Therapeutics)	
	ASP1948/PTZ-329	Antibody	Oncology	Anti-NRP1 antibody	Cancer	P-I	Injection	In-house (Potenza Therapeutics)	
	ASP1951/PTZ-522	Antibody	Oncology	GITR agonistic antibody	Cancer	P-I	Injection	In-house (Potenza Therapeutics)	
	ASP9801	Oncolytic virus	Oncology		Cancer	P-I	Injection	Tottori University [Discovered through collaborative research]	
	ASP7517	Cell therapy (artificial adjuvant vector cells)	Oncology	<u>WT1 loaded artificial adjuvant vector cell</u>	Cancer	P-I	Injection	<u>RIKEN</u> [Discovered through collaborative research]	
Regeneration	ASP7317	Cell therapy	Ophthalmology	Retinal pigment epithelium cells	Dry age-related macular degeneration, Stargardt's disease	P-II	Injection	In-house (Astellas Institute for Regenerative Medicine)	
	FX-322	Small molecule	Otology	Inner ear progenitor cell activator (combination of GSK-3 inhibitor and HDAC inhibitor)	Sensorineural hearing loss	P-II	Injection	Frequency Therapeutics	Astellas has rights in Ex-US markets
Antigen-specific immunomodulation (ASIM)	ASP3772	Next generation vaccine (MAPS technology)	Infectious disease	Pneumococcal vaccine based on a multiple antigen-presenting system (MAPS) platform	Prevention of pneumococcal disease	P-II	Injection	Affinivax	
	ASP0892	Next generation vaccine (LAMP-Vax technology)	Immunology		Peanut allergy	P-I	Injection	Immunomic Therapeutics	
Mitochondria	ASP1128/MA-0217	Small molecule	Nephrology	PPAR $\delta$ modulator	Acute kidney injury	P-II	Injection	In-house (Mitobridge)	
	ASP0367/MA-0211	Small molecule	Muscle disease		Duchenne muscular dystrophy	P-I	Oral	In-house (Mitobridge)	
Others	reldesemtiv CK-2127107	Small molecule	Muscle disease	Fast skeletal muscle troponin activator	Spinal muscular atrophy	P-II	Oral	Cytokinetics	
					Amyotrophic lateral sclerosis	P-II			

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## Others

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Dosage Form	Licensor **	Remarks
Oncology	ASP1650	Antibody	Anti-Claudin 6 monoclonal antibody	Testicular cancer	P-II	Injection	In-house (Ganymed)	
	ASP1235/AGS62P1	Antibody-drug conjugate (ADC)		Acute myeloid leukemia	P-I	Injection	In-house [ADC technology, EuCODE license from Ambrx]	
Urology and Nephrology	solifenacin YM905	Small molecule	Muscarine M <sub>3</sub> receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	US Filed (Feb 2017)	Oral	In-house	
	mirabegron YM178	Small molecule	β <sub>3</sub> receptor agonist	Overactive bladder and neurogenic detrusor overactivity in pediatric patients	P-III	Oral	In-house	
	ASP8302	Small molecule	Muscarine M <sub>3</sub> receptor positive allosteric modulator	Underactive bladder	P-II	Oral	In-house	
Immunology	peficitinib ASP015K	Small molecule	JAK inhibitor	Rheumatoid arthritis	China P-III	Oral	In-house	
	bleselumab ASKP1240	Antibody	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	P-II	Injection	Kyowa Kirin	
	ASP1617	Small molecule		Systemic lupus erythematosus	P-I	Oral	In-house	
Others	fidaxomicin	Small molecule	Macrocyclic antibiotic	<i>Clostridium difficile</i> infection in pediatric patients	Europe Filed (Jan 2019)	Oral	Merck	
	micalfungin	Small molecule	Echinocandin antifungal	Invasive candidiasis in neonates and young infants less than 120 days of life	US Filed (Jun 2019)	Injection	In-house	
	isavuconazole	Small molecule	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients	US P-II	Injection	Basilea	
	ASP0819	Small molecule	Ca <sup>2+</sup> activated K <sup>+</sup> channel opener	Fibromyalgia	P-II	Oral	In-house	
	ASP4345	Small molecule	Dopamine D <sub>1</sub> receptor positive allosteric modulator	Cognitive impairment associated with schizophrenia	P-II	Oral	In-house	
	MucoRice-CTB	Next generation vaccine		Prophylaxis of diarrhea caused by <i>Vibrio cholerae</i>	P-I	Oral	The Institute of Medical Science, the University of Tokyo	
	ASP8062	Small molecule	GABA <sub>B</sub> receptor positive allosteric modulator	Substance use disorders	P-I	Oral	In-house	

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### Update from the previous announcement (Jul 2019):

**evolocumab (AMG 145):** Remove the description of the approval in Japan for familial hypercholesterolemia or hypercholesterolemia in patients who are not suitable for statin therapy in Jun 2019.

**ASP1617:** Entered into Phase 1 for systemic lupus erythematosus.

**AGS-16C3F:** Discontinued the development for renal cell carcinoma because Phase 2 study did not meet its primary endpoint.

**ASP6294:** Discontinued the development for bladder pain syndrome / interstitial cystitis because Phase 2 study did not meet its primary endpoint.

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Patient Journey	New Technology	Content	Code Number/ Program Name	Business Concept	Status	Partner
			Prevention/Therapy	Gamification	Digital healthcare solutions using gamification	Smartphone application
Therapy support	Fluorescence	Image-guided precision surgery	ASP5354	Precision surgery-guide enabling identification of ureter in hysterectomy etc.	Phase I ongoing	
<u>Diagnosis/Therapy</u>	<u>Ultra-small implantable medical devices</u>	<u>Biosensing and treatment measures using ultra-small implantable medical devices</u>				<u>iota Biosciences, Inc.</u>
Diagnosis/Therapy	Radioisotope	Theranostics using antibody with radioisotope label				