

## 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 Apr 2021

Underlined items indicate changes from the previous announcement in Jan 2021.

### 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 *	Licensor **	Remarks
Oncology	enzalutamide MDV3100 (XTANDI®)	Small molecule	Androgen receptor inhibitor	Metastatic castration-sensitive prostate cancer	Europe Filed (Jul 2019) China P-III	Pfizer	
				Non-metastatic castration-sensitive prostate cancer	P-III		
	gilteritinib ASP2215 (XOSPATA®)	Small molecule	FLT3 inhibitor	Relapsed or refractory acute myeloid leukemia	China <u>Approved (Jan 2021)</u>	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		
				Acute myeloid leukemia in pediatric patients	P-III		
	enfortumab vedotin ASG-22ME (PADCEV®)	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Metastatic urothelial cancer, PD-1/PD-L1 inhibitor and platinum-containing chemotherapy pretreated	<u>Europe Filed (Mar 2021)</u>	In-house [Co-development with Seagen]	
				Metastatic urothelial cancer, PD-1/PD-L1 inhibitor pretreated <u>and cisplatin-ineligible</u>	<u>US Filed (Feb 2021)</u>		
				<u>Metastatic urothelial cancer, progressed after anti-cancer medication</u>	<u>Japan Filed (Mar 2021)</u>		
				Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	P-III		
				Muscle-invasive bladder cancer (combo with pembrolizumab)	P-III		
Other solid tumors				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 *	Licensor **	Remarks
Oncology	zolbetuximab IMAB362	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III	In-house (Ganymed)	
				Pancreatic adenocarcinoma	P-II		
Urology and Nephrology	roxadustat ASP1517/FG-4592	Small molecule	HIF-PH inhibitor	Anemia associated with chronic kidney disease	Europe Filed (Apr 2020)	FibroGen	Astellas has rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.
				Chemotherapy-induced anemia	P-II		
Others	fezolinetant ESN364	Small molecule	NK3 receptor antagonist	Vasomotor symptoms associated with menopause	P-III	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.

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

### Updates from the previous announcement (Jan 2021):

**enzalutamide (MDV3100):** Removed the description of the approval in China in Nov 2020 for non-metastatic castration-resistant prostate cancer.

**roxadustat (ASP1517/FG-4592):** Removed the description of the approval in Japan in Nov 2020 for anemia associated with chronic kidney disease in patients not on dialysis.

**gilteritinib (ASP2215):** Obtained the approval in China in Jan 2021 for relapsed or refractory acute myeloid leukemia with a FLT3 mutation.

**enfortumab vedotin (ASG-22ME):** Filed in US in Feb 2021 for the treatment of patients with locally advanced or metastatic urothelial cancer who have been previously treated with a PD-1/PD-L1 inhibitor and are ineligible for cisplatin. Filed in Europe in Mar 2021 for the treatment of patients with locally advanced or metastatic urothelial cancer who have been previously treated with a PD-1/PD-L1 inhibitor and a platinum-containing chemotherapy. Filed in Japan in Mar 2021 for the treatment of patients with locally advanced or metastatic urothelial cancer who have progressed after anti-cancer medication.

Projects with Focus Area approach (1/2)

Target (Biology)	Generic Name Code No. (Brand Name)	Modality / Technology	Therapeutic Area	Classification	Target Disease	Phase *	Licensor **	Remarks
Immunology	ASP1948/PTZ-329	Antibody	Oncology	Anti-NRP1 antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP1951/PTZ-522	Antibody	Oncology	GTR agonistic antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP9801	Oncolytic virus	Oncology	Oncolytic virus carrying IL-7 and IL-12	Cancer	P-I	Tottori University [Discovered through collaborative research]	
	ASP7517	Cell therapy (artificial adjuvant vector cells)	Oncology	WT1 loaded artificial adjuvant vector cell	Cancer	P-I	RIKEN [Discovered through collaborative research]	
	ASP0739	Cell therapy (artificial adjuvant vector cells)	Oncology	NY-ESO-1 loaded artificial adjuvant vector cell	Cancer	P-I	RIKEN [Discovered through collaborative research]	
Regeneration	FX-322	Small molecule	Otology	Inner ear progenitor cell activator (combination of GSK-3 inhibitor and HDAC inhibitor)	Sensorineural hearing loss	P-II	Frequency Therapeutics	Astellas has rights in Ex-US markets
	ASP7317	Cell therapy	Ophthalmology	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration, Stargardt disease	P-I	In-house (Astellas Institute for Regenerative Medicine)	
	ASP0598	Recombinant protein	Otology	Recombinant human heparin-binding epidermal growth factor-like growth factor	Chronic tympanic membrane perforation	P-I	Auration Biotech	
Mitochondria	ASP1128/MA-0217	Small molecule	Nephrology	PPAR $\delta$ modulator	Acute kidney injury	P-II	In-house (Mitobridge)	
	ASP0367/MA-0211	Small molecule	Muscle disease	PPAR $\delta$ modulator	Primary mitochondrial myopathies	P-II	In-house (Mitobridge)	
Duchenne muscular dystrophy					P-I			

**Projects with Focus Area approach (2/2)**

Target (Biology)	Generic Name Code No. (Brand Name)	Modality / Technology	Therapeutic Area	Classification	Target Disease	Phase *	Licensors **	Remarks
Genetic regulation	resamirigene bilparvovec AT132	Gene therapy (AAV-based gene therapy)	Muscle disease	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	P-II	In-house (Audentes Therapeutics)	
	AT845	Gene therapy (AAV-based gene therapy)	Muscle disease	GAA gene replacement to express GAA enzyme	Pompe disease	P-I	In-house (Audentes Therapeutics)	
Others	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	Affinivax	
	ASP0892	Next generation vaccine (LAMP-vax technology)	Immunology		Peanut allergy	P-I	Immunomic Therapeutics	
	ASP2390	New generation vaccine (LAMP-vax technology)	Immunology		House dust mite-induced allergic rhinitis	P-I	Immunomic Therapeutics [Discovered through collaborative research]	

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## Others

Therapeutic Area	Generic Name Code No. (Brand Name)	Modality / Technology	Classification	Target Disease	Phase *	Licensor **	Remarks
Urology and Nephrology	mirabegron YM178	Small molecule	$\beta_3$ receptor agonist	Neurogenic detrusor overactivity in pediatric patients	US <u>Approved (Mar 2021)</u> Europe P-III	In-house	
				Overactive bladder in pediatric patients	Europe P-III		
Immunology	tacrolimus FK506 (Prograf <sup>®</sup> )	Small molecule	Immunosuppressant	Prevention of rejection after lung transplantation	US Filed (Dec 2020)	In-house	
	peficitinib ASP015K	Small molecule	JAK inhibitor	Rheumatoid arthritis	China P-III	In-house	
	bleseelumab ASKP1240	Antibody	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients	P-II	Kyowa Kirin	
	ASP1617	Small molecule		Systemic lupus erythematosus	P-I	In-house	
Others	isavuconazole	Small molecule	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients	US P-II	Basilea	
	ASP8062	Small molecule	GABA <sub>B</sub> receptor positive allosteric modulator	<u>Opioid use disorder</u>	P-II	In-house	
				Alcohol use disorder	P-I		

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### Update from the previous announcement (Jan 2021):

**mirabegron (YM178):** Obtained the approval in US in Mar 2021 for neurogenic detrusor overactivity in pediatric patients aged three years and older.

**ASP8062:** Entered into Phase 2 for opioid use disorder.

## Rx+ Program

As of Apr 2021

Underlined item indicates changes from the previous announcement in Jan 2021

Sphere (Business area)	Project	Concept	Status	Partner	Remarks
Chronic disease progression prevention	Smartphone application	Offer smartphone application to support exercise using wearable device to people who needs regular exercise	Under development	BANDAI NAMCO Entertainment	
	Fitness service (Fit-eNce)	Scientifically evidenced exercise programs and systems which support regular exercise	Launched in limited areas		
	BlueStar	Digital therapeutics for adults with diabetes	Under development	Welldoc	
	<u>Program for Holter analysis devices (My Holter II)</u>	<u>AI-based data analysis program for Holter electrocardiography test</u>	<u>Japan</u> <u>Certified as a medical device (Mar 2021)</u>	<u>M. Heart</u>	
Patient outcome maximization	ASP5354	Precision surgery-guide enabling identification of ureter in hysterectomy and colorectal surgery etc.	P-II		

### Update from the previous announcement (Jan 2021)

**Program for Holter analysis devices (My Holter II):** Added as a new project.