

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 2022

Underlined items indicate changes from the previous announcement in Feb 2022.

XTANDI and Strategic products (1/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
enzalutamide MDV3100 (XTANDI)	Small molecule	Androgen receptor inhibitor	Metastatic castration-sensitive prostate cancer	China P-III	Pfizer	
			Non-metastatic castration-sensitive prostate cancer	P-III		
gilteritinib ASP2215 (XOSPATA)	Small molecule	FLT3 inhibitor	Post-chemotherapy maintenance acute myeloid leukemia	P-III	In-house	
			Post-hematopoietic stem cell transplant maintenance acute myeloid leukemia	P-III		
			Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	P-III		
			Newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy	P-I		
			Acute myeloid leukemia in pediatric patients	P-III		
enfortumab vedotin ASG-22ME (PADCEV)	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Metastatic urothelial cancer, platinum-containing chemotherapy and PD-1/L1 inhibitor pretreated	Europe <u>Approved (Apr 2022)</u>	In-house [Co-development with Seagen]	
			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		
			Non-muscle-invasive bladder cancer	P-I		

XTANDI and Strategic products (2/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
zolibetuximab IMAB362	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	P-III	In-house (Ganymed)	
			Pancreatic adenocarcinoma	P-II		
roxadustat ASP1517/FG-4592 (EVRENZO)	Small molecule	HIF-PH inhibitor	Chemotherapy-induced anemia	P-II	FibroGen	Astellas has rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa
fezolinetant ESN364	Small molecule	NK3 receptor antagonist	Vasomotor symptoms associated with menopause	P-III	In-house (Ogeda)	
resamirigene bilparovect AT132	Gene therapy (AAV-based gene therapy)	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	P-II	In-house (Audentes Therapeutics)	

* 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 (Feb 2022):

enfortumab vedotin (ASG-22ME): Obtained the approval in Europe in Apr 2022 for locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a PD-1/L1 inhibitor.

Projects with Focus Area approach (1/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensors **	Remarks
Immuno-oncology	ASP9801	Oncolytic virus	Oncolytic virus carrying IL-7 and IL-12	Cancer	P-I	Tottori University [Discovered through collaborative research]	
	ASP7517	Cell therapy (artificial adjuvant vector cells)	WT1 loaded artificial adjuvant vector cell	Acute myeloid leukemia and myelodysplastic syndrome	P-II	RIKEN [Discovered through collaborative research]	
				Solid tumor	P-I		
	ASP0739	Cell therapy (artificial adjuvant vector cells)	NY-ESO-1 loaded artificial adjuvant vector cell	Cancer	P-I	RIKEN [Discovered through collaborative research]	
	ASP1570	Small molecule	DGKζ inhibitor	Cancer	P-I	In-house	
ASP2138	Antibody	Anti-Claudin 18.2 and anti-CD3 bispecific antibody	Gastric and gastroesophageal junction adenocarcinoma, pancreatic adenocarcinoma	P-I	Xencor [Discovered through collaborative research]		
Blindness and Regeneration	ASP7317	Cell therapy	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration, Stargardt disease	P-I	In-house (Ocata Therapeutics)	
Mitochondria Biology	bocidelpar ASP0367/MA-0211	Small molecule	PPARδ modulator	Primary mitochondrial myopathies	P-II	In-house (Mitobridge)	
				Duchenne muscular dystrophy	P-I		
	ASP8731/ML-0207	Small molecule	BACH1 inhibitor	Sickle cell disease	P-I	In-house (Mitobridge)	

Projects with Focus Area approach (2/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
Genetic regulation	resamirigene bilparvovec AT132 ***	Gene therapy (AAV-based gene therapy)	MTM1 gene replacement to express myotubularin	X-linked myotubular myopathy	P-II	In-house (Audentes Therapeutics)	
	AT845	Gene therapy (AAV-based gene therapy)	GAA gene replacement to express GAA enzyme	Pompe disease	P-I	In-house (Audentes Therapeutics)	
(Other projects with Focus Area approach)	FX-322	Small molecule	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
	ASP0598	Recombinant protein	Recombinant human heparin-binding epidermal growth factor-like growth factor	Chronic tympanic membrane perforation	P-I	Auration Biotech	
	ASP3082	Small molecule		Cancer	P-I	In-house	

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*** AT132 is also listed in "XTANDI and Strategic products".

Updates from the previous announcement (Feb 2022):

ASP8731/ML-0207: Entered into Phase 1 for sickle cell disease.

ASP3082: Entered into Phase 1 for cancer.

ASP1951/PTZ-522: Discontinued Phase 1 program for cancer.

ASP1128/MA-0217: Discontinued the development for acute kidney injury because Phase 2 study did not meet its primary endpoint.

ASP3772: Discontinued the development for prevention of pneumococcal disease in Phase 2 due to strategic prioritization.

ASP2390: Discontinued Phase 1 program for house dust mite-induced allergic rhinitis.

Others

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
mirabegron YM178	Small molecule	β_3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	Europe P-III	In-house	
			Overactive bladder in pediatric patients	Europe P-III		
peficitinib ASP015K	Small molecule	JAK inhibitor	Rheumatoid arthritis	China P-III	In-house	
isavuconazole	Small molecule	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients	US P-II	Basilea	
ASP8062	Small molecule	GABA _B receptor positive allosteric modulator	Opioid use disorder	P-II	In-house	
			Alcohol use disorder	P-I		

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Rx+ Program

As of Apr 2022

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Sphere (Business area)	Program	Concept	Status *	Partner	Remarks
Chronic disease progression prevention	Game application for exercise support	Smartphone application to support exercise using motion sensing technology for people who needs regular exercise	Under development	BANDAI NAMCO Entertainment	
	Fit-eNce	Service to provide scientifically evidenced exercise programs and systems supporting regular exercise	Under test marketing		
	Fit-eNce Home	Service to provide scientifically evidenced exercise programs and systems supporting regular exercise at home	Under test marketing		
	BlueStar	Digital therapeutics for adults with diabetes	<u>Under clinical trial preparation</u>	Welldoc	
Patient outcome maximization	pudexacianinium chloride ASP5354	Precision surgery-guide enabling identification of ureter in hysterectomy and colorectal surgery etc.	P-III		

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Updates from the previous announcement (Feb 2022)

BlueStar: Entered into clinical trial preparation phase.