

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 Jul 2023

Underlined items indicate changes from the previous announcement in Apr 2023.

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	<u>US</u> <u>Submitted (Jun 2023)</u> <u>Europe</u> 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	China Filed (Mar 2023)	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		
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		

XTANDI and Strategic products (2/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensors **	Remarks
zolibetuximab IMAB362	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma	Japan Filed (Jun 2023) US Filed (Jul 2023) Europe Filed (Jul 2023) China Filed (Jul 2023)	In-house (Ganymed)	
			Pancreatic adenocarcinoma	P-II		
fezolinetant ESN364 (VEOZAH)	Small molecule	NK3 receptor antagonist	Vasomotor symptoms due to menopause	US Approved (May 2023) Europe Filed (Sep 2022) China P-III Japan P-II	In-house (Ogeda)	
avacincaptad pegol	Pegylated RNA aptamer	Complement C5 inhibitor	Geographic atrophy secondary to age-related macular degeneration	US Filed (Feb 2023) Europe Submitted (Jul 2023)	In-house (Iveric Bio)	
			Stargardt disease	P-I		
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 (Apr 2023):

enzalutamide: sNDA submitted in US in Jun 2023 for non-metastatic hormone-sensitive prostate cancer with high-risk biochemical recurrence.

enfortumab vedotin: Removed the description of the approval in US in Apr 2023 for unresectable locally advanced or metastatic urothelial cancer who are ineligible to receive cisplatin-based chemotherapy in the first-line setting.

zolibetuximab: Filed in Japan in Jun 2023, US, Europe, and China in Jul 2023 for gastric and gastroesophageal junction adenocarcinoma.

fezolinetant: Approved in US in May 2023 for vasomotor symptoms due to menopause.

avacincaptad pegol: Added a program.

Projects with Focus Area approach (1/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
Immuno-oncology	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]	
	ASP2074	Antibody	Bispecific antibody	Cancer	P-I	In-house	
	ASP1002	Antibody	Bispecific antibody	Cancer	P-I	In-house	
Blindness and Regeneration	ASP7317	Cell therapy	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration	P-I	In-house (Ocata Therapeutics)	
Mitochondria	bocidelpar ASP0367/MA-0211	Small molecule	PPARδ modulator	Primary mitochondrial myopathies	P-II	In-house (Mitobridge)	
				Duchenne muscular dystrophy	P-I		

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)	
Targeted Protein Degradation	ASP3082	Small molecule	KRAS G12D degrader	Cancer	P-I	In-house	

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

Updates from the previous announcement (Apr 2023):

ASP7317: In accordance with the current status of the project, the description of Stargardt disease in the Phase 1 has been removed as its development is now in the research phase.

ASP0598: Discontinued the Phase 1 program for chronic tympanic membrane perforation.

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 Filed (Aug 2022)	In-house	
isavuconazole	Small molecule	Azole antifungal	Invasive aspergillosis and mucormycosis in pediatric patients	US <u>Submitted (Jun 2023)</u>	Basilea	
ASP8062	Small molecule	GABA _B receptor positive allosteric modulator	Alcohol use disorder	P-I	In-house	

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Updates from the previous announcement (Apr 2023):

isavuconazole: sNDA submitted in Jun in the US for invasive aspergillosis and mucormycosis in pediatric patients.

Rx+ Program

As of July 2023

Category	Program	Concept	Status*	Partner	Remarks
Digital health Other services	Fit-eNce	Service to provide scientifically evidenced exercise programs and systems supporting regular exercise	Under feasibility study		
	Fit-eNce Home	Service to provide scientifically evidenced exercise programs and systems supporting regular exercise at home	Under feasibility study		
	BlueStar	Digital therapeutics for adults with diabetes	Under clinical trial preparation	Welldoc Roche Diabetes Care Japan	
Drug-device combination	pudexacianinium chloride ASP5354	Intraoperative ureter visualization for use in patients undergoing minimally invasive and open abdominopelvic surgeries	P-III	Stryker	
		Visualization and localization of lymph nodes in patients with breast cancer or melanoma undergoing lymphatic mapping	P-II		

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