

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 2024

Underlined items indicate changes from the previous announcement in Apr 2024.

XTANDI and Strategic Brands (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 <u>Approved (Jun 2024)</u>	Pfizer	
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 Pfizer]	
			Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	Europe Filed (Jan 2024) Japan Filed (Jan 2024) China Filed (Mar 2024)		
			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 Brands (2/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
zolibetuximab IMAB362 (VYLOY)	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma (combo with chemotherapy)	US Filed (May 2024) Europe Filed (Jul 2023) China Filed (Jul 2023)	In-house (Ganymed)	
			<u>Gastric and gastroesophageal junction adenocarcinoma (combo with checkpoint inhibitor and chemotherapy)</u>	P-III		
			Pancreatic adenocarcinoma	P-II		
fezolinetant ESN364 (VEOZAH***)	Small molecule	NK3 receptor antagonist	Vasomotor symptoms due to menopause	China P-III Japan P-III	In-house (Ogeda)	
			Induced vasomotor symptoms in breast cancer patients on adjuvant endocrine therapy	P-III		
avacincaptad pegol (IZERVAY)	Pegylated RNA aptamer	Complement C5 inhibitor	Geographic atrophy secondary to age-related macular degeneration	Europe Filed (Aug 2023)		
			Stargardt disease	P-II		

* 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.

*** Approved as "VEOZA" in ex-US.

Updates from the previous announcement (Apr 2024):

enzalutamide: Approved in China in Jun 2024 for metastatic castration-sensitive prostate cancer. Removed the description of the approval in Europe for high risk biochemical recurrent non-metastatic hormone sensitive prostate cancer that is unsuitable for salvage radiotherapy in Apr 2024.

zolibetuximab: Removed the description of the approval in Japan for CLDN18.2 positive, unresectable, advanced or recurrent gastric cancer in Mar 2024. Resubmission filed in US in May 2024 for gastric and gastroesophageal junction adenocarcinoma (combo with chemotherapy). Entered into Phase 3 for gastric and gastroesophageal junction adenocarcinoma (combo with checkpoint inhibitor and chemotherapy).

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	ASP1570	Small molecule	DGK ζ 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]	
	ASP1002	Antibody	<u>Anti-Claudin 4 and anti-CD137 bispecific antibody</u>	Cancer	P-I	In-house	
	ASP1012	Oncolytic virus	Oncolytic virus encoding leptin-IL-2	Cancer	P-I	KaliVir	
	ASP2802	Cell therapy	CD20 autologous <i>convertible</i> CAR-T	B-cell lymphoma	P-I	In-house (Xyphos Biosciences)	
Targeted Protein Degradation	ASP3082	Small molecule	KRAS G12D degrader	Cancer	P-I	In-house	
	ASP4396	Small molecule	KRAS G12D degrader	Cancer	P-I	In-house	

Projects with Focus Area approach (2/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensors **	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)	
	zocaglusagene nuzaparvovec AT845	Gene therapy (AAV-based gene therapy)	GAA gene replacement to express GAA enzyme	Pompe disease	P-I	In-house (Audentes Therapeutics)	
	ASP2016	Gene therapy (AAV-based gene therapy)	FXN gene replacement to express frataxin	Cardiomyopathy associated with Friedreich ataxia	P-I	In-house (Audentes Therapeutics)	
Blindness and Regeneration	ASP7317	Cell therapy	Retinal pigment epithelium cells	Geographic atrophy secondary to age-related macular degeneration	P-I	In-house (Ocata Therapeutics)	
Immune Homeostasis ***	ASP5502	Small molecule	STING inhibitor	Primary Sjogren's syndrome	P-I	In-house	

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*** Primary Focus Candidate.

Updates from the previous announcement (Apr 2024):

ASP1002: Described the classification.

ASP5502: Entered into Phase 1.

Others

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensors **	Remarks
mirabegron YM178	Small molecule	β_3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients (aged 3 to less than 18 years)	Europe Filed	In-house	
			Neurogenic detrusor overactivity in pediatric patients (aged 6 months to less than 3 years)	Europe P-III		
peficitinib ASP015K	Small molecule	JAK inhibitor	Rheumatoid arthritis	China Filed (Aug 2022)	In-house	
roxadustat ASP1517/FG-4592	Small molecule	HIF-PH inhibitor	Anemia associated with chronic kidney disease in pediatric patients	Europe P-III	FibroGen	Astellas has rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.
abiraterone decanoate PRL-02/ASP5541	Small molecule	CYP17 lyase inhibitor	Prostate cancer	P-I	In-house (Propella Therapeutics)	

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Rx+ Program

As of Jul 2024

Category	Program	Concept	Status*	Partner	Remarks
Digital health Other services	BlueStar	Digital therapeutics for adults with diabetes	Pivotal study (Japan)	Welldoc Roche Diabetes Care Japan	
	Z1608	Digital therapeutic plus remote patient monitoring for heart failure	Under development	Welldoc Eko	
Drug-device combination	pudexacianinium chloride ASP5354	Intraoperative ureter visualization for use in patients undergoing minimally invasive and open abdominopelvic surgeries	P-III	Stryker	

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