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 Feb 2025

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

Strategic Brands (1/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
enfortumab vedotin **ASG-22ME** **(PADCEV)**	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Metastatic urothelial cancer, previously untreated (first line; combo with pembrolizumab)	China Approved (Jan 2025)	In-house [Co-development with Pfizer]	
			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-II		
			Acute myeloid leukemia in pediatric patients	P-III		

Strategic Brands (2/2)

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
zolbetuximab **IMAB362** **(VYLOY)**	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma (combo with chemotherapy)	China Approved (Dec 2024)	In-house (Ganymed)	
			Gastric and gastroesophageal junction adenocarcinoma (combo with checkpoint inhibitor and chemotherapy)	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	Stargardt disease	P-II	In-house (Iveric Bio)	

* 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 (Oct 2024):
enfortumab vedotin: Removed the description of the approval in China for metastatic urothelial cancer, platinum-containing chemotherapy and PD-1/L1 inhibitor pretreated in Aug 2024. Removed the description of the approval in Europe for the first-line treatment of unresectable or metastatic urothelial cancer (eligible for platinum-containing chemotherapy) in Aug 2024. Removed the description of the approval in Japan for the first-line treatment of radically unresectable urothelial carcinoma in Sep 2024. Approved in China in Jan 2025 for locally advanced or metastatic urothelial cancer.
gilteritinib: Entered into Phase 2 for newly diagnosed acute myeloid leukemia with low intensity induction of chemotherapy.
zolbetuximab: Removed the description of the approval in US in Oct 2024 and in Europe in Sep 2024 for the first-line treatment of locally advanced unresectable or metastatic HER2-negative, claudin 18.2-positive gastric or gastroesophageal junction adenocarcinoma. Approved in China in Dec 2024 for locally advanced unresectable or metastatic HER2-negative, claudin 18.2-positive gastric or gastroesophageal junction adenocarcinoma.
avacincaptad pegol: Removed the description of the withdrawal in EU for geographic atrophy secondary to age-related macular degeneration in Oct 2024.

Programs with Focus Area approach

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]	
	ASP1002	Antibody	Anti-Claudin 4 and anti-CD137 bispecific antibody	Cancer	P-I	In-house	
	ASP1012	Oncolytic virus	Oncolytic virus encoding leptin-IL-2	Cancer	P-I	KaliVir	
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	
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)	
Blindness and Regeneration	**ASP7317**	Cell therapy	Retinal pigment epithelial cells	Geographic atrophy secondary to age-related macular degeneration	P-I	In-house (Ocata 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 (Oct 2024):
ASP2802: Discontinued Phase 1 program for B-cell lymphoma.
ASP2016: Discontinued Phase 1 program for cardiomyopathy associated with Friedreich ataxia.

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 (aged 6 months to less than 3 years)	Europe P-III	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 **ASP5541 (PRL-02)**	Small molecule	CYP17 lyase inhibitor	Prostate cancer	P-I	In-house (Propella Therapeutics)	
ASP5502	Small molecule	STING inhibitor	Primary Sjogren's syndrome	P-I	In-house	

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

Updates from the previous announcement (Oct 2024):
mirabegron: Removed the description of the approval in Europe for neurogenic detrusor overactivity in pediatric patients (aged 3 to less than 18 years) in Aug 2024.
peficitinib: Removed the description of the approval in China for rheumatoid arthritis in Jul 2024.

Rx+ Program

As of Feb 2025

Underlined items indicate changes from the previous announcement in Oct 2025.

Category	Program	Concept	Status*	Partner	Remarks
Digital health	**BlueStar**	Digital health therapeutic for the management of diabetes	Pivotal study (Japan)	Welldoc Roche Diabetes Care Japan	
	DIGITIVA **Z1608**	Non-invasive digital health solution for management of heart failure	Commercially available	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	
Implantable medical device	**Implantable bladder device**	Implantable device for underactive bladder	FDA approved to enter into early feasibility study	(iota Biosciences)	

* The list shows the most advanced stage if the stages are different depending on the region.

Updates from the previous announcement (Oct 2024):
DIGITIVA: Initial commercialization in November 2024.