

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 2025

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

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	Muscle-invasive bladder cancer (combo with pembrolizumab)	P-III	In-house [Co-development with Pfizer]	
			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 *	Licensors **	Remarks
zolbetuximab IMAB362 (VYLOY)	Antibody	Anti-Claudin 18.2 monoclonal antibody	Gastric and gastroesophageal junction adenocarcinoma (combo with pembrolizumab and chemotherapy)	P-III	In-house (Ganymed)	
			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)	
			Vasomotor symptoms in breast cancer patients on adjuvant endocrine therapy	P-III		
avacincaptad pegol (IZERVAY)	Pegylated RNA aptamer	Complement C5 inhibitor	<u>Geographic atrophy secondary to age-related macular degeneration</u>	Japan <u>Filed (Feb 2025)</u>		
			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.

<p><b>Updates from the previous announcement (Feb 2025):</b></p> <p><b>enfortumab vedotin:</b> Removed the description of the approval in China for locally advanced or metastatic urothelial cancer in Jan 2025.</p> <p><b>zolbetuximab:</b> Removed the description of the approval in China for locally advanced unresectable or metastatic HER2-negative, claudin 18.2-positive gastric or gastroesophageal junction adenocarcinoma in Dec 2024.</p> <p><b>avacincaptad pegol:</b> Submitted in Japan in Feb 2025 for geographic atrophy secondary to age-related macular degeneration.</p>
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## Programs with Focus Area approach

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
Immunology	ASP1570	Small molecule	DGK $\zeta$ 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-II	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)	

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### Updates from the previous announcement (Feb 2025):

**AT845:** Entered into Phase 2 for pompe disease.

## Others

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
<b>mirabegron</b> <b>YM178</b>	Small molecule	$\beta_3$ receptor agonist	Neurogenic detrusor overactivity in pediatric patients (aged 6 months to less than 3 years)	Europe P-III	In-house	
<b>roxadustat</b> <b>ASP1517/FG-4592</b>	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.
<b>abiraterone decanoate</b> <b>ASP5541 (PRL-02)</b>	Small molecule	CYP17 lyase inhibitor	Prostate cancer	P-I	In-house (Propella Therapeutics)	
<b>ASP5502</b>	Small molecule	STING inhibitor	Primary Sjogren's syndrome	P-I	In-house	

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Rx+ Program

As of Apr 2025

Category	Program	Concept	Status*	Partner	Remarks
Digital health	BlueStar	Digital therapeutic for the management of diabetes	Pivotal study (Japan)	Welldoc Roche Diabetes Care Japan	
	DIGITIVA	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)	

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