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 2021

Underlined items indicate changes from the previous announcement in Apr 2021.

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	Europe Approved (Apr 2021) 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 low intensity induction of chemotherapy	P-III		
			Newly diagnosed acute myeloid leukemia with high intensity induction of chemotherapy	P-III		
			Acute myeloid leukemia in pediatric patients	P-III		
enfortumab vedotin ASG-22ME (PADCEV)	Antibody-drug conjugate (ADC)	Nectin-4 targeted ADC	Metastatic urothelial cancer, PD-1/PD-L1 inhibitor and platinum-containing chemotherapy pretreated	Europe Filed (Mar 2021)	In-house [Co-development with Seagen]	
			Metastatic urothelial cancer, cisplatin-ineligible and who have previously received one or more therapy	US Approved (Jul 2021)		
			Metastatic urothelial cancer, progressed after anti-cancer medication	Japan Filed (Mar 2021)		
			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
zolbetuximab **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**	Small molecule	HIF-PH inhibitor	Anemia associated with chronic kidney disease	Europe Filed (Apr 2020)	FibroGen	Astellas has rights in Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.
			Chemotherapy-induced anemia	P-II		
fezolinetant **ESN364**	Small molecule	NK3 receptor antagonist	Vasomotor symptoms associated with menopause	P-III	In-house (Ogeda)	
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)	

* 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 2021):
gilteritinib (ASP2215): Removed the description of the approval in China in Jan 2021 for relapsed or refractory acute myeloid leukemia with a FLT3 mutation.
enzalutamide (MDV3100): Obtained the approval in Europe in Apr 2021 for metastatic hormone-sensitive prostate cancer.
enfortumab vedotin (ASG-22ME): Obtained the approval in US in Jul 2021 for metastatic urothelial cancer, cisplatin-ineligible and who have previously received one or more therapy. Entered into Phase 1 for non-muscle-invasive bladder cancer.

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	**ASP1948/PTZ-329**	Antibody	Anti-NRP1 antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	ASP1951/PTZ-522	Antibody	GITR agonistic antibody	Cancer	P-I	In-house (Potenza Therapeutics)	
	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	Cancer	P-I	RIKEN [Discovered through collaborative research]	
	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		Cancer	P-I	In-house	
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	**ASP1128/MA-0217**	Small molecule	PPARδ modulator	Acute kidney injury	P-II	In-house (Mitobridge)	
	ASP0367/MA-0211	Small molecule	PPARδ modulator	Primary mitochondrial myopathies	P-II	In-house (Mitobridge)	
				Duchenne muscular dystrophy	P-I		
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)	

Projects with Focus Area approach (2/2)

Primary Focus	Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
(Other projects with Focus Area approach)	**ASP3772**	Next generation vaccine (MAPS technology)	Pneumococcal vaccine based on a multiple antigen-presenting system (MAPS) platform	Prevention of pneumococcal disease	P-II	Affinivax	
	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	
	ASP2390	New generation vaccine (LAMP-Vax technology)		House dust mite-induced allergic rhinitis	P-I	Immunomic Therapeutics [Discovered through collaborative research]	

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

Updates from the previous announcement (Apr 2021):
ASP1570: Entered into Phase 1 for cancer.
ASP0892: Discontinued Phase 1 program for peanut allergy.

Others

Generic name Code No. (Brand name)	Modality / Technology	Classification	Target disease	Phase *	Licensor **	Remarks
tacrolimus **FK506** **(Prograf)**	Small molecule	Immunosuppressant	Prevention of rejection after lung transplantation	US Approved (Jul 2021)	In-house	
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		
ASP1617	Small molecule		Systemic lupus erythematosus	P-I	In-house	

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Update from the previous announcement (Apr 2021):
mirabegron (YM178): Removed the description of the approval in US in Mar 2021 for neurogenic detrusor overactivity in pediatric patients aged three years and older.
tacrolimus (FK506): Obtained the approval in US in Jul 2021 for prevention of organ rejection in adult and pediatric patients receiving lung transplantation.
bleselumab (ASKP1240): Discontinued the development for recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients because Phase 2 study did not meet its primary endpoint.

Rx+ Program

As of Jul 2021

Sphere (Business area)	Program	Concept	Status *	Partner	Remarks
Chronic disease progression prevention	**Game application for exercise support**	Smartphone application to support exercise using wearable device for people who needs regular exercise	Under development	BANDAI NAMCO Entertainment	
	Fit-eNce	Scientifically evidenced exercise programs and systems which support regular exercise	Launched in limited areas New service model under development		
	BlueStar	Digital therapeutics for adults with diabetes	Under development	Welldoc	
Patient outcome maximization	**ASP5354**	Precision surgery-guide enabling identification of ureter in hysterectomy and colorectal surgery etc.	P-II		

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

Updates from the previous announcement (Apr 2021)
My Holter II: Removed the description of the program which obtained certification in Mar 2021.