

R&D pipeline

small molecule
 large molecule
 antibody
 HSC-GT
 Updated since Dec. 31, 2023
 Updated since Mar. 31, 2024

As of Jun. 30, 2024

Code Name Generic Name Formulation		Mechanism of Action	Indication	Stage			[In-House or Licensed] Remarks
				PhI	PhII	PhIII	
	KK8123 Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia				[In-House] Preparation underway for PhI as a global product
	KK2845	Anti-TIM-3 ADC	Acute Myelogenous Leukemia				[In-House] Antibody-Drug Conjugate Preparation underway for PhI in Japan as a global product
	OTL-203	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IH (Hurler Syndrome)				[In-House] Rare Pediatric Disease (RPD) and Fast Track designations (FDA) Priority Medicines (PRIME) designation (EMA) Area of clinical study: NA and EU
	OTL-201	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IIIA (Sanfilippo Syndrome type A)				[In-House] Rare Pediatric Disease (RPD) designation (FDA) Preparation underway for registrational study (equivalent to PhIII study)
	KHK4083/AMG 451 rocatinlimab Injection	Anti-OX40 Antibody	Moderate to Severe Atopic Dermatitis				[In-House] POTELLIGENT Human monoclonal antibody production technology Collaboration agreement with Amgen for the development of rocatinlimab in all the countries except for Japan. Clinical study is being conducted in JP, NA, EU, UK, Middle East, Asia, Oceania, and other regions as a global product
			Moderate to Severe Asthma				Clinical study is being conducted in JP, NA, EU, Asia, and Oceania as a global product
			Prurigo Nodularis				Preparation underway for PhIII as a global product
	KHK4951 tivozanib Ophthalmic	VEGF Receptor Tyrosine Kinase Inhibitor	Diabetic Macular Edema				[In-House] Clinical study is being conducted in JP, NA, Asia, and Oceania as a global product
			Neovascular Age-Related Macular Degeneration				Clinical study is being conducted in JP, NA, Asia, and Oceania as a global product
	KK2260 Injection	EGFR-TfR1Bispecific Antibody	Solid Tumor				[In-House] REGULGENT Fully human antibody production technology A clinical study is being conducted in JP, and a clinical study is prepared under way for Ph I in NA as a global product.
	KK2269 Injection	EpCAM-CD40Bispecific Antibody	Solid Tumor				[In-House] REGULGENT Fully human antibody production technology Clinical study is being conducted in JP and NA as a global product
	AMG531 romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Previously Untreated with Immunosuppressive Therapy				[Amgen K-A] product name in Japan: Romiplate Area of clinical study: Asia
	KK4277 Injection	Anti-PTPRS Humanized Antibody	Systemic Lupus Erythematosus/Cutaneous Lupus Erythematosus				[SBI Biotech] POTELLIGENT Clinical study is being conducted in JP and Asia

Major Applications and Approvals

Code Name, Generic Name, Product Name	Indication	Application/Under Review	Countries/Regions Received Approval in 2024
KRN125(pegfilgrastim, Product name in Japan:G-LASTA)	Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation	–	JP
OTL-200(atidarsagene autotemcel, Product name in Europe/US : Libmeldy/Lenmeldy)	Metachromatic Leukodystrophy	–	US
KHK4827(brodalumab, Product name in Japan and Asia: Lumicef)	Systemic Sclerosis	JP	–
	Palmoplantar Pustulosis	TW	–
KHK7580(evocalcet, Product name in Japan: Orkedia)	Secondary Hyperparathyroidism	–	CN, TW
AMG531(romiplostim, Product name in Japan: Romiplate)	Aplastic Anemia	TW	–
	Severe Aplastic Anemia	KR	–