R&D pipeline

small m　antibody　HSC-GT　Updated since Dec. 31, 2024　✓ Updated since Sep. 30, 2025

As of Dec 31, 2025

Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage	[In-House or Licensed] Remarks
KK8123 Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia	PhI	[In-House] Clinical study is being conducted in NA and EU as a global product
KK8398 infigratinib Oral	FGFR3 Inhibitor	Achondroplasia	PhI → PhII → ✓PhIII	[QED Therapeutics] Clinical study is being conducted in JP
		Hypochondroplasia		Preparation underway for Ph Ⅲ clinical trial in JP
ziftomenib ※ Oral	Menin Inhibitor	Acute Lymphoblastic Leukemia（ALL）（Monotherapy）	PhI	[Kura Oncology] Clinical study is being conducted in NA and EU as a global product KMT2A-rearranged ALL KOMET-001
		Acute Myeloid Leukemia (AML)（Monotherapy）	PhI → PhII → PhIII	Clinical study is being conducted in NA and EU as a global product Non-NPM1-mutant AML/Non-KMT2A-rearranged AML KOMET-001
				Adult Relapsed or Refractory AML with a NPM1 Mutation Preparation underway for Ph Ⅱ clinical trial in JP
		Acute Myeloid Leukemia (AML)（Combination）	PhI → PhII → PhIII	Clinical study is being conducted in NA as a global product NPM1-mutant AML/KMT2A-rearranged AML Combinations with venetoclax + azacitidine, and cytarabine + daunorubicin KOMET-007
			✓PhI → PhII → PhIII	Clinical study is being conducted in NA as a global product FLT3/NPM1 co-mutated AML Combinations with cytarabine + daunorubicin, and quizartinib KOMET-007
			PhI → PhII → PhIII	Clinical study is being conducted in NA and EU a global product NPM1-mutant AML/KMT2A-rearranged AML Combinations with gilteritinib, FLAG-IDA, LDAC KOMET-008
			PhI → PhII → PhIII	Clinical study is being conducted as a global product NPM1-mutant AML/KMT2A-rearranged AML Combinations with venetoclax + azacitidine, and cytarabine + daunorubicin KOMET-017
KK2845	Anti-TIM-3 ADC	Acute Myeloid Leukemia（AML）	PhI	[In-House] Antibody-Drug Conjugate Clinical study is being conducted in JP as a global product
OTL-203	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IH (Hurler Syndrome)	PhI → PhII → PhIII	[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)	PhI → PhII / PhⅠ	[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	PhI → PhII → PhIII	[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
		Prurigo Nodularis	PhI → PhII → PhIII	Clinical study is being conducted in JP, NA, EU, Asia, and Oceania as a global product
		Moderate to Severe Asthma	PhI → PhII	Clinical study is being conducted in JP, NA, EU, Asia, and Oceania as a global product

※ For detailed information on ziftomenib(Product Name in US: KOMZIFTI)'s development status, please refer to Kura Oncology's website. https://kuraoncology.com/

Code Name Generic Name Formulation	Mechanism of Action	Indication	Stage			[In-House or Licensed] Remarks
			PhI	PhII	PhIII	
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	Advanced or Metastatic Solid Tumors				[In-House] REGULGENT Fully human antibody production technology Clinical study is being conducted in JP, and a clinical study is prepared under way for PhI in NA as a global product
KK2269 Injection	EpCAM-CD40Bispecific Antibody	Advanced or Metastatic Solid Tumors				[In-House] REGULGENT Fully human antibody production technology Clinical study is being conducted in JP and NA as a global product
KK4277 Injection	Anti-PTPRS Humanized Antibody	Systemic Lupus Erythematosus/Cutaneous Lupus Erythematosus				[SBI Biotech] POTELLIGENT Clinical study is being conducted in JP and Asia
KK3910 Injection		Essential Hypertension				[In-House] Clinical study is being conducted in JP as a global product
OTL-200 atidarsagene autotemcel	Hematopoietic Stem Cell (HSC) Gene Therapy	Early-onset Metachromatic Leukodystrophy (MLD)				[In-House] Orphan Regenerative Medicine Product Designation in JP Preparation underway for clinical trial in JP Product Name in US: Lenmeldy Product Name in Europe: Libmeldy

※ On January 30, 2026, Kyowa Kirin announced that termination of the current KHK4083/AMG 451 (rocatinlimab) collaboration with Amgen and Kyowa Kirin will regain control of KHK4083/AMG 451 development and commercialization program.

Major Applications and Approvals

As of Dec. 31, 2025

Code Name, Generic Name, Product Name	Indication	Application/Under Review	Countries/Regions Received Approval in 2025
ziftomenib(Product name in the US: KOMZIFTI)	Adult Relapsed or Refractory (R/R) Acute Myeloid Leukemia (AML) with a Nucelophosmin1 (NPM1) Mutation	–	US
KHK4827(brodalumab, Product name in Japan and Asia: Lumicef)	Palmoplantar Pustulosis	–	TW