主な開発品の治験概要

2020年12月31日現在

協和キリン株式会社

本資料の内容は表紙に記載した時点における情報です。治験の進捗に伴い、治験データベース上の公開情報は随時更新されます。弊社が実施中の治験に関する最新情報につきましては、以下URLをご参照ください。
https://clinicaltrials.gov/
https://www.clinicaltrials.jp/

弊社の開発パイプラインの全体像は、以下URLよりご覧いただけます。
https://www.kyowakirin.co.jp/research_development_production/pipeline/index.html

List of abbreviations

AE	Adverse Events
DLT	Dose Limiting Toxicity
GFR	Glomerular Filtration Rate
iv	Intravenous
MTD	Maximum Tolerated Dose
ORR	Overall Response Rate
PD	Pharmacodynamics
PFS	Progression Free Survival
PK	Phamacokinetics
po	Peroral
Q2W	Every Two Weeks
Q4W	Every Four Weeks
Q12W	Every Twelve Weeks
QD	Once Daily
QW	Once Weekly
sc	Subcutaneous

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
AMG531	PⅢ	Aplastic anemia	JP/KR	Single-Arm trial Weekly SC administration	**Primary Outcome Measures:** Proportion of subjects achieving a hematological response **Secondary Outcome Measures:** 1. Proportion of subjects with a hematological response at the end-of- treatment examination 2. Time from the first romiplostim administration to hematological response 3. In subjects receiving platelet transfusion as a pretreatment within 8 weeks prior to the first romiplostim administration; proportion of subjects with transfusion independence or decreased platelet transfusion requirement 4. Proportion of subjects achieving platelet response, erythroid response, or neutrophil response at each of Week 27 and end of treatment.	20-Dec	N=46	NCT02773290	JapicCTI-163243
AMG531	PⅡ	Aplastic anemia	KR	Randomized Parallel Assignment Open Label	**Primary Outcome Measures:** The proportion of subjects achieving a platelet response	17-Nov	N=35	NCT02094417	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				Arm1:Dose1 Weekly SC Arm2:Dose2 Weekly SC Arm3:Dose3 Weekly SC Arm4:Dose4 Weekly SC	**Secondary Outcome Measures:** 1. The proportion of subjects achieving a platelet response 2. The proportion of subjects who become platelet transfusion independent 3. The proportion of subjects achieving erythroid response 4. The proportion of subjects achieving neutrophil response 5. Changes in Gruppo Italiano Malattie Ematologiche Maligne dell' Adulto (GIMEMA) bleeding scale 6. Profiles of Pharmacokinetics 7. Pharmacokinetic parameters, including Tmax, Cmax and (AUC)0-t, will be assessed. 8. Incidences of adverse events				
AMG531	P Ⅱ / Ⅲ	Aplastic anemia	JP/KR/TW	Single-Arm trial SC administration Initial dose is 10 ug/kg/. Maximum dose is 20 ug/kg	**Primary Outcome Measures:** Achievement of complete response (CR) or partial response (PR) **Secondary Outcome Measures:** 1. Achievement of CR or PR	December 2021	N=14	NCT03957694	JapicCTI-194746

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					2. Achievement of CR 3. The time to CR or PR 4. Reduction or independence of platelet and/or erythrocyte transfusion 5. Change from baseline in platelet count (/μL) 6. Change from baseline in hemoglobin (Hb) concentration (g/dL) 7. Change from baseline in neutrophil count (/μL) 8. Change from baseline in reticulocyte count (/μL)				
AMG531	P Ⅱ / Ⅲ	Aplastic anemia	JP/KR	Single-Arm Trial SC administration of 0 to 20ug/kg for 6 months	**Primary Outcome Measures:** Rate of achievement of CR or PR **Secondary Outcome Measures:** 1. Rate of achievement of CR or PR [2. Rate of achievement of C 3. The time to CR or PR 4. Reduction or independence of platelet and/or erythrocyte transfusion 5. Change from baseline in platelet count (/μL) 6. Change from baseline in hemoglobin (Hb)	August 2021	N=24	NCT04095936	JapicCTI-194962

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					concentration (g/dL) 7. Change from baseline in neutrophil count (/μL) 8. Change from baseline in reticulocyte count (/μL)				
AMG531	PⅠ/Ⅱ	Immune Thrombocytopenia (ITP)	CN	Randomized Parallel Assignment Open Label - Experimental: 1 mcg/kg AMG531 - Experimental: 3 mcg/kg AMG531	**Primary Outcome Measures:** The incidence of all adverse events including evaluation of antidrug antibody status	August 2017	N=16	NCT02868060	
AMG531	PⅢ	Immune Thrombocytopenia	CN	multi-center, Randomized, Placebo-controlled, Double-blinded then Open-label - Placebo Comparator: Placebo	**Primary Outcome Measures:** Number of weeks in which the platelet response counts increase above 50×10^9/L **Secondary Outcome Measures:** 1. Proportion of subjects whose platelet counts relative to the baseline increase ≥ 20×10^9/L 2.Proportion of subjects who have received	June 2017	N=203	NCT02868099	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				- Experimental: Drug	emergency treatment to increase the platelet counts				
ASKP1240	P Ⅰ	Healthy Volunteers	US	Randomized Parallel Assignment Arm A: lowest dose Arm B: second lowest dose Arm C: third lowest dose Arm D: fourth lowest dose Arm E: fifth lowest dose Arm F: middle dose Arm G: sixth highest dose Arm H: fifth highest dose Arm I: fourth highest dose Arm J: third highest	**Primary Outcome Measures:** 1. Pharmacodynamic variable: Individual subject cell surface antigen (CD40) occupancy levels over time 2. Pharmacokinetics profile: AUCinf and Cmax **Secondary Outcome Measures:** 1. Pharmacokinetics profile: AUClast, tmax, t1/2, Vz, and CLtot 2. Total lymphocyte counts 3. Peripheral lymphocyte subset quantification 4. Safety assessed by recording adverse events, laboratory assessments, vital signs, electrocardiograms (ECGs), physical examination, pulse oximetry, and incidence of anti-ASKP1240 antibody formation	December 2009	N=109	NCT01565681	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				dose Arm K: second highest dose Arm L: highest dose Arm M: Placebo					
ASKP1240	P Ⅰb	Kidney Transplantation	US	Randomized Parallel Assignment Double-blind Arm1: lowest dose Arm2: low dose Arm3: high dose Arm4: highest dose Arm5: Placebo	**Primary Outcome Measures:** Pharmacokinetic assessment through analysis of blood samples	January 23, 2012	N=50	NCT01279538	
ASKP1240	P Ⅰ	Healthy Volunteers	US	Randomized Parallel Assignment Open Label Arm A: IV infusion Arm B: SC	**Primary Outcome Measures:** Pharmacokinetic profile: AUClast, AUCinf, and F **Secondary Outcome Measures:** 1. Pharmacodynamic profile: CD40 receptor occupancy over time 2. Pharmacodynamic profile: Total lymphocyte count and peripheral lymphocyte subset	September 2012	N=24	NCT01582399	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					quantification 3. Pharmacokinetics profile: Cmax, Tmax, t1/2, Vz, and CLtot				
ASKP1240	P Ⅱa	Psoriasis	AU, CA, NZ	Randomized Parallel Assignment Double-blind Cohort 1: lowest dose iv Cohort 2: low dose iv Cohort 3: high dose iv Cohort 4: highest dose iv Placebo	**Primary Outcome Measures:** 1. Pharmacokinetics of ASKP1240: AUC336 2. Pharmacokinetics of ASKP1240: Cmax 3. Pharmacodynamic variable: CD40 receptor occupancy on peripheral blood B cells 4. Characterize safety profile of ASKP1240 through adverse event reporting, vital signs, clinical laboratory evaluations, physical examinations and 12-lead electrocardiograms (ECGs) **Secondary Outcome Measures:** 1. Mean change from baseline to 8 weeks in Psoriasis Area Severity Index (PASI) score 2. Mean change from baseline to 8 weeks in Physicians Static Global Assessment (PSGA) score 3. Proportion of Subjects Achieving Treatment Success	January 2015	N=60	NCT01585233	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					4. Success of the treatment of psoriasis is defined as a score of 1 (almost clear) or 0 (clear) as measured by the PSGA 5. Mean change from baseline to 8 weeks in % Body Surface Area (BSA) 6. Cytokine Concentration 7. Anti-ASKP1240 antibodies 8. Lymphocyte subset quantitation				
ASKP1240	P Ⅱa	Kidney Transplantation	US	Randomized Parallel Assignment Open Label Standard of Care: Basiliximab induction + Tacrolimus + MMF + Corticosteroids CNI avoidance: Basiliximab induction + ASKP1240 + MMF + Corticosteroids	**Primary Outcome Measures:** Biopsy-proven acute (T or B cell) rejection (BPAR) (Banff 2007 Grade ≥ 1) by local review **Secondary Outcome Measures:** 1. Glomerular Filtration Rate (GFR) 2. Patient Survival 3. Graft Survival	January 27, 2017	N=149	NCT01780844	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				CNI minimization-MMF avoidance: Basiliximab induction + ASKP1240 + Tacrolimus + Corticosteroids					
ASKP1240	P Ⅱa	Kidney Transplantation Focal Segmental Glomerulosclerosis (FSGS)	US/CA	Randomized Parallel Assignment Open Label - Standard of Care regimen: (basiliximab induction, tacrolimus, methylprednisone, prednisone and MMF). - Bleselumab regimen: (basiliximab, methylprednisone, prednisone, bleselumab and tacrolimus).	**Primary Outcome Measures:** Recurrence of focal segmental glomerulosclerosis (FSGS) defined as nephrotic range proteinuria with protein-creatinine ratio (≥ 3.0 g/g) through 3 months post-transplant. **Secondary Outcome Measures:** 1. Recurrence of FSGS defined as nephrotic range proteinuria with protein-creatinine ratio (≥ 3.0 g/g). 2. Biopsy-proven acute rejection (BPAR) (Banff Grade ≥ 1, local read) 3. Efficacy failure 4. Biopsy-proven (blinded, central read) rFSGS	April 2021	N=60	NCT02921789	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
KHK2455	P Ⅰ	Solid Tumor Cancer Carcinoma	US/FR	Part 1 (Dose Escalation Part): KHK2455 monotherapy [Cycle 0] followed by KHK2455 +mogamulizumab combination [Cycle 1]. Part 2 (Expansion Part): Subjects with a selected tumor type will be enrolled and treated with the recommended dose of KHK2455 established in Part 1 in combination with mogamulizumab.	**Primary Outcome Measures:** Number of Participants with Adverse Events as a Measure of Safety and Tolerability	October 2020	N=50	NCT02867007	
KHK2455	P Ⅰ	Urothelial Carcinoma	US	KHK2455 in Combination with Avelumab	**Primary Outcome Measures:** Number of participants with treatment-related adverse events as assessed by CTCAE v.5.0	February 25, 2022	N=44	NCT03915405	
KHK4083	P Ⅰ	Dermatitis, Atopic	JP	KHK4083 iv	**Primary Outcome Measures:** Incidence of treatment-emergent adverse events (TEAEs) or drug-related TEAEs and their	February 7, 2018	N=26	NCT03096223	JapicCTI-173543

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					nature **Secondary Outcome Measures:** 1. Serum KHK4083 concentration 2. Maximum concentration (Cmax) 3. Time to reach Cmax (tmax) 4. Area under the curve (AUC) 5. Anti-KHK4083 antibody production				
KHK4083	P Ⅱ	Atopic Dermatitis	US/CA/ DE/JP	Randomized Parallel Assignment Arm A Placebo sc Arm B KHK4083 (dose level 1, dosing regimen 2) sc Arm C KHK4083 (dose level 2, dosing regimen 1) sc Arm D KHK4083 (dose level 3, dosing regimen 1) sc	**Primary Outcome Measures:** **Percent change from baseline to Week 16 in EASI** **Secondary Outcome Measures:** **1. EASI-50, EASI-75, or EASI-90** **2. Change in EASI score** **3. Change and percent change from baseline in SCORAD score** **4. Achievement of an IGA score of 0 or 1 and a reduction from baseline of ≥2 points** **5. Change in percent BSA** **6. Change and percent change in pruritus NRS score**	February 2021	N=250	NCT03703102	JapicCTI-184115

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				Arm E KHK4083 (dose level 3, dosing regimen 2) sc	**7. Change and percent change in sleep disturbance NRS score** **8. Change in DLQI** **9. Change and percent change in EASI score** **10. Achievement of EASI-50, EASI-75, or EASI-90** **11. Change and percent change in SCORAD score** **12. Achievement of an IGA score of 0 or 1 and a reduction from baseline of ≥2 points** **13. Change in percent BSA** **14. Change and percent change in pruritus NRS score** **15. Change and percent change in sleep disturbance NRS score** **16. Change in DLQI**				
KHK4827	P Ⅰ	Psoriasis	Japan	Randomized Parallel Assignment Single # Experimental: KHK4827	**Primary Outcome Measures:** 1. Safety 2. Adverse events 3. Clinical laboratory test data 4. Vital signs	September 2012	N=48	NCT01488201	JapicCTI-173543

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				#Placebo Comparator: Placebo	**Secondary Outcome Measures:** Plasma KHK4827 concentrations and pharmacokinetic parameters				
KHK4827	P Ⅱ	Moderate to Severe Plaque Psoriasis	Japan	Randomized Parallel Assignment Double-blind # KHK4827 70mg SC # KHK4827 140mg SC # KHK4827 210mg SC # Placebo SC	**Primary Outcome Measures:** Percent improvement from baseline in PASI at Week 12 **Secondary Outcome Measures:** 1. PASI 75 2. PASI 50, 90 and 100 3. sPGA of "clear or almost clear (0 or 1)" 4. sPGA of "clear (0)" 5. BSA involvement of lesion 6. ACR 20% response (only in subjects with psoriasis arthritis) 7. Incidence and types of adverse events and adverse reactions Profiles of Pharmacokinetics	September 2013	N=140	NCT01748539	JapicCTI-122023
KHK4827	P Ⅲ	Psoriasis	Japan	Randomized Parallel Assignment	**Primary Outcome Measures:** 1. Incidence and types of adverse events and adverse reactions 2. Laboratory values and vital signs	February 2015	N=145	NCT01782924	JapicCTI-132056

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				# KHK4827 140mg SC # KHK4827 210mg SC	3. Development of anti-KHK4827 antibody **Secondary Outcome Measures:** 1. Percent improvement from baseline in PASI 2. PASI 50, PASI 75, PASI 90 and PASI 100 response 3. sPGA of "clear or almost clear (0 or 1)" 4. sPGA of "clear (0)" 5. BSA involvement of lesion 6. ACR 20 (only in subjects with psoriasis arthritis) 7. Profiles of pharmacokinetics				
KHK4827	PⅢ	Psoriasis	Japan	Single Group Assignment Open Label # KHK4827 140mg	**Primary Outcome Measures:** Clinical Global Impression (CGI) **Secondary Outcome Measures:** 1. Percent improvement from baseline in PASI 2. ACR 20 (only in subjects with psoriasis arthritis) 3. Pustular symptom score (only in subjects with pustular psoriasis) 4. sPGA of "clear or almost clear (0 or 1)" (only	December 2014	N=30	NCT01782937	JapicCTI-132057

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					in subjects with psoriatic erythroderma) 5. sPGA of "clear (0)" (only in subjects with psoriatic erythroderma) 6. BSA involvement of lesion 7. Incidence and types of adverse events and adverse reactions 8. Laboratory values and vital signs 9. Profiles of pharmacokinetics 10. Development of anti-KHK4827 antibody				
KHK4827	PⅢ	Psoriasis Vulgaris Psoriatic Arthritis Pustular; Psoriasis, Palmaris Et Plantaris Psoriatic Erythroderma	Japan	Non-Randomized Parallel Assignment Open Label # KHK4827 140mg SC # KHK4827 210mg SC	**Primary Outcome Measures:** 1. Incidence and types of adverse events and adverse reactions 2. Anti-KHK4827 antibody **Secondary Outcome Measures:** 1. Change in PASI compared to the data obtained before the first dose of investigational product in this study. 2. Percent improvement in PASI 3. PASI 50, 75, 90, and 100 4. sPGA of "0 (clear) or 1(almost clear)" 5. sPGA of "0 (clear)	July 4, 2016	N=155	NCT02052609	JapicCTI-142430

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					6. Change in BSA of lesion 7. CGI 8. ACR 20 9. Pustular symptom score 10Serum KHK4827 concentration				
KHK4827	PⅢ	Moderate to Severe Plaque Psoriasis	KR	Randomized Parallel Assignment Doubl-blind - KHK4827 SC injection - Placebo Comparator: Placebo	**Primary Outcome Measures:** 1. PASI 75 response 2. sPGA of "0 (clear)" or "1 (almost clear)" **Secondary Outcome Measures:** 1. PASI 50/75/90/100 response by visit 2. sPGA of "0 (clear) or 1 (almost clear)" by visit 3. BSA involvement of lesion 4. NAPSI score (applicable only to subjects who had nail symptoms at baseline) 5. PSSI score (applicable only to subjects who had scalp symptoms at baseline) 6. DLQI 7. TEAEs or drug-related TEAEs 8. Laboratory values 9. Vital signs	August 14, 2018	N=62	NCT02982005	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					10. Anti-KHK4827 antibodies 11. Serum KHK4827 concentration				
KHK4827	P Ⅰ	Systemic Sclerosis	JP	Single Group Assignment Open Label - KHK4827 210 mg Q2W, SC	**Primary Outcome Measures:** Serum KHK4827 concentration **Secondary Outcome Measures:** Change in modified Rodnan skin score (mRSS) from baseline	March 31, 2023	N=8	NCT04368403	JapicCTI-173686
KHK4827	PⅢ	Moderate to Severe Systemic Sclerosis	JP	Randomized Parallel Assignment Double-blind - Experimental: KHK4827 210 mg Q2W, SC - Placebo Comparator: Placebo	**Primary Outcome Measures:** Change in modified Rodnan skin score (mRSS) from baseline at Week 24 **Secondary Outcome Measures:** Change in modified Rodnan skin score (mRSS) from baseline at Week 52	March 31, 2023	N=100	NCT03957681	JapicCTI-194761
KHK4827	PⅢ	Palmoplantar Pustulosis	JP	Randomized Parallel Assignment Double-blind	**Primary Outcome Measures:** Change from baseline in Palmoplantar Pustulosis Area and Severity Index (PPPASI) total score at Week 16	March 2021	N=120	NCT04061252	JapicCTI-194862

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				- Experimental: KHK4827 210mg Q2W SC - Placebo Comparator: Placebo Q2W SC	**Secondary Outcome Measures:** 1. Change from baseline in PPP-SI total score 2. The percentage of participants who achieved at least 50% improvement in PPPASI score 3. The percentage of participants who achieved at least 75% improvement in PPPASI score 4. The percentage of participants who achieved a PGA score of 0 or 1 5. Change in PPPASI total score 6. Change in PPP-SI total score at each assessment time point 7. Change in DLQI score				
KHK4827	PⅢ	Axial Spondyloarthritis	JP/KR/TW	Randomized Parallel Assignment Double-blind - KHK4827 administered SC - Placebo administered SC	**Primary Outcome Measures:** Percentage of ASAS 40 in axSpA subjects **Secondary Outcome Measures:** 1. Percentage of ASAS 40 in AS subjects 2. Percentage of ASAS 40 in nr-axSpA subjects 3. ASDAS-CRP change from baseline in axSpA subjects 4. Number of adverse events	September 23, 2019	N=159	NCT02985983	JapicCTI-163449

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					5. Number of patients exposed to anti-KHK4827 antibodies 6. Serum KHK4827 concentration				
KHK4951	P Ⅰ	Healthy Volunteers Wet Age-related Macular Degeneration	JP	Randomized Sequential Assignment - Experimental: KHK4951 - Placebo Comparator: Placebo	**Primary Outcome Measures :** 1. Number of participants with adverse events **Secondary Outcome Measures :** 1. Serum KHK4951 concentration 2. Time to the maximum concentration 3. The maximum concentration 4. Area under the concentration-time curve 5. Apparent clearance	February 2022	N=96	NCT04594681	
KHK6640	P Ⅰ	Alzheimer's Disease	BE/NL/RS/SE	Randomized Parallel Assignment Double-blind - Experimental: KHK6640 - Placebo Comparator: Placebo	**Primary Outcome Measures:** Number of Participants with Adverse Events	May 2017	N=57	NCT02127476	
KHK6640	P Ⅰ	Alzheimer's Disease	JP	Randomized Parallel Assignment	**Primary Outcome Measures:** Number of Participants with Adverse Events	September 2016	N=20	NCT02377713	JapicCTI-152818

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				Double-blind - Experimental: KHK6640 - Placebo Comparator: Placebo					
KHK6640	P Ⅰ	Alzheimer's Disease	JP	Randomized Parallel Assignment Double-blind - Experimental: KHK6640 - Placebo Comparator: Placebo	**Primary Outcome Measures:** Number of Participants with Adverse Events	December 6, 2017	N=21	NCT03093519	JapicCTI-173541
KHK7580	P Ⅰ / Ⅱ	Hyperparathyroidism	JP	Single Group Assignment - KHK7580 Oral adminisrtration	**Primary Outcome Measures:** The safety of KHK7580 assessed by number and types of adverse events, laboratory tests, vital signs, electrocardiogram and ophthalmic examination **Secondary Outcome Measures:**	March 2014	N=20	NCT01935856	JapicCTI-132255

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					1. Profiles of pharmacokinetics 2. Profiles of pharmacodynamics				
KHK7580	P Ⅰ	Secondary Hyperparathyroidism	JP	Single Group Assignment - KHK7580 Oral adminisrtration	**Primary Outcome Measures:** Number and types of adverse events **Secondary Outcome Measures:** Profiles of pharmacokinetics	December 2014	N=13	NCT02143271	JapicCTI-142537
KHK7580	P Ⅱb	Secondary Hyperparathyroidism	JP	Randomized Parallel Assignment Double-blind - Placebo Comparator: Plascebo - Experimental: KHK7580 low dose - Experimental: KHK7580 middle dose - Experimental: KHK7580 high dose - Active Comparator: KRN1493	**Primary Outcome Measures:** The percent changes in intact PTH levels from baseline **Secondary Outcome Measures:** 1. Intact PTH, whole PTH, corrected serum Ca, ionized Ca, serum phosphorus, intact FGF 23 and corrected serum Ca X serum phosphorus 2. Safety	February 2015	N=201	NCT02216656	JapicCTI-142631

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
KHK7580	PⅢ	Secondary Hyperparathyroidism	JP	Randomized Parallel Assignment Double-blind - Experimental: KHK7580 - Active Comparator: KRN1493	**Primary Outcome Measures:** Percentage of subjects in the evaluation period achieving a mean intact PTH level of ≥ 60 pg/mL and ≤ 240 pg/mL **Secondary Outcome Measures:** 1. Percentage of subjects in the evaluation period achieving a mean percent decrease in intact PTH level of ≥ 30% (percent change ≤ −30%) from baseline 2. Mean percent change in the evaluation period in intact PTH level from baseline	November 2016	N=634	NCT02549391	JapicCTI-153013
KHK7580	PⅢ	Secondary Hyperparathyroidism	JP	Single Group Assignment - KHK7580	**Primary Outcome Measures:** Number of participants with adverse events **Secondary Outcome Measures:** 1. Percentage of subjects achieving intact PTH level of ≥ 60 pg/mL and ≤ 240 pg/mL 2. Percentage of subjects achieving a mean percent decrease in intact PTH level of ≥ 30% (percent change ≤ −30%) from baseline	December 28, 2016	N=137	NCT02549404	JapicCTI-153015

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					3. Mean percent change in intact PTH level from baseline				
KHK7580	PⅢ	Secondary Hyperparathyroidism	JP	Single Group Assignment - KHK7580	**Primary Outcome Measures:** Percentage of subjects in the evaluation period achieving a mean intact PTH level of ≥ 60 pg/mL and ≤ 240 pg/mL **Secondary Outcome Measures:** 1. Percentage of subjects in the evaluation period achieving a mean percent decrease in intact PTH level of ≥ 30% (percent change ≤ −30%) from baseline 2. Mean percent change in the evaluation period in intact PTH level from baseline	December 22, 2016	N=39	NCT02549417	JapicCTI-153016
KHK7580	PⅢ	Parathyroid Carcinoma Primary Hyperparathyroidism	JP	Single Group Assignment - KHK7580	**Primary Outcome Measures:** Percentage of subjects whose corrected serum calcium level is maintained ≤ 10.3 mg/dL for 2 weeks in the evaluation period **Secondary Outcome Measures:** 1. Percentage of subjects whose corrected serum calcium level decreases by ≥1.0 mg/dL	April 9, 2019	N=10	NCT03280264	JapicCTI-173684

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					from baseline and the decrease is maintained for 2 weeks in the evaluation period. 2. Corrected serum calcium level 3. intact PTH level 4. whole PTH level				
KHK7580	PⅢ	Secondary Hyperparathyroidism	CN/KR/TW/HK	Randomized Parallel Assignment Double-blind #Experimental: KHK7580 #Active Comparator: Cinacalcet	**Primary Outcome Measures:** Mean percent change in intact PTH level from baseline in the evaluation period **Secondary Outcome Measures:** 1. Number of subjects achieving a mean intact PTH level of ≧150pg/mL and ≦300pg/mL in the evaluation period 2. Percentage of subjects achieving a mean intact PTH level of ≧150pg/mL and ≦ 300pg/mL in the evaluation period 3. Number of subjects achieving a mean percent decrease in intact PTH level of ≧30% (percent change ≦-30%) from baseline in the evaluation period 4. Percentage of subjects achieving a mean percent decrease in intact PTH level of ≧30%	June 2021	N=400	NCT03822507	

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					(percent change ≦-30%) from baseline in the evaluation period 5. Intact PTH level 6. corrected serum Ca level serum P level				
KHK7580	P Ⅰ	Healthy Volunteer	CN	Non-Randomized Sequential Assignment Open Label - 1mg KHK7580 po - 3mg KHK7580 po - 6mg KHK7580 po - 12mg KHK7580 po - 6mg KHK7580 for 8days	**Primary Outcome Measures:** 1. Plasma KHK7580 concentration 2. Time to Reach Tmax 3. Cmax of KHK7580 4. AUC0-t 5. AUCinf 6. t1/2 7. CL/F **Secondary Outcome Measures:** 1. Incidence of TEAEs 2. QTcF 3. QTcB 4. intact PTH level 5. serum P level	December 2020	N=42	NCT04206657	
KHK7791	P Ⅱ	Hyperphosphatemia	JP	Randomized Parallel Assignment	**Primary Outcome Measures:** To investigate the clinically recommended dose	December 31, 2019	N=207	NCT03864458	JapicCTI-194626

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				Double-blind - Arm A: KHK7791 low dose BID. - Arm B: KHK7791 middle dose BID. - Arm C: KHK7791 high dose BID. - Arm D: KHK7791 high dose and down titrate. - Arm E: Placebo BID.	by comparing changes in serum phosphorus levels from baseline values at Week 6 **Secondary Outcome Measures:** 1. Changes in serum Ca × P levels 2. Changes in corrected serum calcium levels				
KHK7791	P Ⅱ	Hyperphosphatemia	JP	Randomized Parallel Assignment Double-blind	**Primary Outcome Measures:** Comparing changes in serum phosphorus levels between hemodialysis patients taking KHK7791 in combination with phosphate binders and those taking placebo in combination with	December 3, 2019	N=47	NCT03864445	JapicCTI-194625

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				- KHK7791 BID - Placebo BID	phosphate binders. **Secondary Outcome Measures:** 1. Changes in serum Ca × P levels 2. Changes in corrected serum calcium levels				
KHK7791	P Ⅱ	Hyperphosphatemia	JP	Single Group Assignment - KHK7791 Patients start at KHK7791 30 mg BID and can down titrate weekly to 20, 15, 10, and 5 mg BID, sequentially based on a GI tolerability question.	**Primary Outcome Measures:** Percentage of subjects who reduce the total number of taking phosphate binder tablets at the last assessment from baseline **Secondary Outcome Measures:** 1. Serum phosphorus levels 2. Corrected serum calcium level	November 26, 2019	N=67	NCT03831607	JapicCTI-184562
KRN125	P Ⅱ	Peripheral Blood Stem Cell Transplantation	JP	Single Group Assignment Single center, open label, non-control, dose setting study	**Primary Outcome Measures:** Achievement of >20 cells/μL positive for CD34 in peripheral blood from baseline to Day 7 **Secondary Outcome Measures:** • Period from baseline to first time peripheral	December 2020	N=41	NCT03993639	JapicCTI-194774

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				- KRN125 Single dose of SC administration	blood CD34 positive cells >20 cells/μL • Time from baseline to peak peripheral blood CD34 positive cells • Achievement of >10 cells/μL positive for CD34 in peripheral blood from baseline to Day 7 • Peripheral blood CD34 positive cell count • Peripheral blood white blood cell count • Peripheral blood neutrophil count				
KRN125	P Ⅰ	Breast Cancer	JP	multicenter, uncontrolled, open-label study - 3.6 mg administered subcutaneously once per chemotherapy cycle	**Primary Outcome Measures:** Safety - Adverse events - Laboratory examination - Vital Signs **Secondary Outcome Measures:** Exploratory (concentrations in sera)	March 31 2021	N=30		JapicCTI-205130
KRN23	PⅢ	XLH	JP/KR	Single Group Assignment Open Label - SC injections of KRN23	**Primary Outcome Measures:** 1. Number of subjects for each adverse event 2. Body temperature 3. Pulse rate 4. Respiratory rate 5. SBP in sitting position	December 31, 2020	N=27	NCT04308096	

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				every 4 weeks (adult) 2 weeks (pediatric)	6. DBP in sitting position 7. Effect to 12-lead ECG 8. Effect to renal ultrasound 9. Effect to Echocardiogram **Secondary Outcome Measures:** 1. Concentration of serum phosphorus 2. Concentration of serum 1,25(OH)2D 3. Concentration of urinary phosphorus 4. Tubular reabsorption of phosphate from 2-hour urine 5. Concentration of maximum tubular reabsorption of TmP/GFR 6. Carboxy terminal cross-linked telopeptide of type 1 collagen (CTx) 7. P1NP 8. BALP 9. Concentration of serum ALP (Pediatric patients with XLH) 10. Motor functions (6MWT) 11. Radiographic findings of fracture and enthesopathy (Adult patients with XLH) 12. RSS				

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					13. RGI-C 14. Z score of height (LMS method) (Pediatric patients with XLH) **Other Outcome Measures:** 1. Pharmacokinetics (Serum KRN23 concentration) 2. Immunogenicity (Anti-KRN23 Antibody)				
KRN23	P Ⅱ	Tumor-Induced Osteomalacia or Epidermal Nevus Syndrome	JP/KR	Single Group Assignment Open Labe - SC injections of KRN23 Q4W from Week 0 through Week 44	**Primary Outcome Measures:** Serum phosphorus concentration **Secondary Outcome Measures:** 1. ALP 2. 1,25(OH)2D 3. urine P 4. tubular reabsorption of phosphate 5. renal tubular maximum phosphate reabsorption rate to glomerular filtration rate 6. skeletal disease/osteomalacia through trans-iliac crest bone biopsy 7. STS test 8. HHD	December 2020	N=6	NCT02722798	JapicCTI-163191

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					9. WAL test 10. 6MWT 11. patient reported outcomes 12. KRN23 Cmax 13. KRN23 AUC 14. KRN23 t1/2 Other Outcome Measures: Number and types of adverse events				
KW-0761	PⅢ	HTLV-1 Associated Myelopathy	JP	Randomized Parallel Assignment Double-blind - Experimental: KW-0761 0.3 mg/kg IV - Placebo Comparator: Placebo (saline)	**Primary Outcome Measures:** Improvement in Osame's motor disability score **Secondary Outcome Measures:** 1. HTLV-1 Proviral load in peripheral blood 2. Mean of twice 10 m walking time 3. Modified Ashworth Scale 4. Evaluation of Clinical Global Impression (CGI-I) 5. Evaluation of Clinical Global Impression (VAS) 6. Evaluation of Urinary dysfunction (OABSS) 7. Evaluation of Urinary dysfunction (I-PSS) 8. Evaluation of sensory dysfunction (numbness	December 2020	N=66	NCT03191526	JapicCTI-173608

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					in the lower limbs (VAS)) 9. Evaluation of sensory dysfunction (Pain in the lower limbs (VAS)) 10. Neopterine Concentration in CSF				
KW-0761	P Ⅰ	Adult T-Cell Leukemia and Lymphoma (ATL) Adult Peripheral T-Cell Lymphoma (PTCL)	JP	Single Group Assignment Open Label # KW-0761 IV administration at 4 escalating dose levels.	**Primary Outcome Measures:** 1. Incidence of Dose-Limiting Toxicities (DLTs) 2. Maximum Tolerated Dose (MTD) 3. Pharmacokinetics-Plasma KW-0761 Concentrations 4. Pharmacokinetics-Pharmacokinetic Parameters of KW-0761 (AUC0-7 Days) 5. Pharmacokinetics-Pharmacokinetic Parameters of KW-0761 (t1/2) **Secondary Outcome Measures:** 1. Antitumor Effect 2. Time to Progression (TTP)	October 2008	N=16	NCT00355472	
KW-0761	P Ⅱ	Adult T-cell Leukemia-lymphoma	JP	Single Group Assignment Open Label - KW-0761 is	**Primary Outcome Measures:** 1. Overall Response Rate (ORR) 2. Pharmacokinetics-Plasma KW-0761 Concentrations 3. Pharmacokinetics-Plasma KW-0761	November 2010	N=28	NCT00920790	JapicCTI-090772

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				administered weekly for 8 weeks as an intravenous infusion of 2 hours at a dose of 1.0 mg/kg.	Concentrations (AUC0-7days) 4. Pharmacokinetics-Plasma KW-0761 Concentrations (t1/2 **Secondary Outcome Measures:** 1. Progression Free Survival (PFS) 2. Overall Survival (OS)				
KW-0761	P Ⅱ	Adult T-cell Leukemia-Lymphoma	JP	Randomized Parallel Assignment Open Label - Active Comparator: mLSG15 - Experimental: mLSG15 + KW-0761	**Primary Outcome Measures:** Complete response rate in the best overall response assessment for antitumor effect **Secondary Outcome Measures:** 1. Response rate in the best overall response assessment for antitumor effect, complete or response rates by lesion site in the best overall response assessment for antitumor effect 2. Progression-free survival and Overall survival 3. Adverse event 4. anti-KW-0761 antibody 5. Plasma KW-0761 concentrations and pharmacokinetic parameters	April 2012	N=44	NCT01173887	JapicCTI-101209

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
KW-0761	P Ⅱ	Peripheral T/NK-cell Lymphoma	JP	Single Group Assignment - KW-0761 Intravenously 8 times at 1-week intervals	**Primary Outcome Measures:** Antitumor effect **Secondary Outcome Measures:** 1. Antitumor effect (best response by disease lesion), progression-free survival and overall survival 2. Adverse events and anti-KW-0761 antibody levels 3. Plasma KW-0761 concentrations and pharmacokinetic parameters	May 2012	N=38	NCT01192984	JapicCTI-101256
KW-0761	P Ⅰ/ Ⅱ	Peripheral T-Cell Lymphoma	US	Single Group Assignment Open Label - KW-0761 open label, dose escalation (0.1, 0.3, 1.0 mg/kg)	**Primary Outcome Measures:** Maximum Tolerated Dose **Secondary Outcome Measures:** time to progression	September 2012	N=42	NCT00888927	
KW-0761	P Ⅱ	Peripheral T-cell Lymphoma	US	Single Group Assignment Open Label	**Primary Outcome Measures:** To determine a Global Composite Response (skin, blood, lymph nodes) as determined by	September 2012	N=1	NCT01226472	

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
		Cutaneous T-cell Lymphoma		- In the first treatment course KW-0761 will be administered i.v. once a week for four weeks, followed by a 2-week observation period. Subsequent treatment courses are permissible for subjects demonstrating a response or maintaining stable disease and will consist of an infusion of KW-0761 every other week.	skin evaluations, blood counts and PET/CT imaging **Secondary Outcome Measures:** To determine the number of participants with adverse events as a measure of safety and tolerability.				
KW-0761	P Ⅱ	Peripheral T-Cell Lymphoma	DK/FR/IT/NL/ES/UK	Single Group Assignment Open Label - intravenously weekly x	**Primary Outcome Measures:** Overall Response Rate	May 2015	N=38	NCT01611142	

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				4 then every other week until progression					
KW-0761	P Ⅱ	Adult T-cell Leukemia-Lymphoma	US/BE/BR/FR/PE/UK	Randomized Parallel Assignment Open Label - Experimental: KW-0761 - Comparator is investigator's choice of pralatrexate or gemcitabine plus oxaliplatin or DHAP	**Primary Outcome Measures:** Overall Response Rate **Secondary Outcome Measures:** 1. Progression Free Survival 2. Overall Survival 3. Change in Functional Assessment of Cancer Therapy-Lymphoma (FACT-Lym) Total Score	February 2018	N=71	NCT01626664	
KW-0761	P Ⅲ	Cutaneous T-Cell Lymphoma	US/AU/DE/FR/DE/IT/JP/NL/EP/CH/UK	Randomized Parallel Assignment Open Label - Experimental: KW-0761	**Primary Outcome Measures:** Progression Free Survival **Secondary Outcome Measures:** 1. Overall Response Rate 2. Quality of Life (QoL) Assessment - Skindex-29 Symptoms Scale Score 3. Pruritis Evaluation	December 2020	N=372	NCT01728805	

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				- Active Comparator: Vorinostat					
KW-3357	PⅢ	Preeclampsia	JP	Randomized Parallel Assignment Double Blind - Experimental: KW-3357: 72 IU/kg - Placebo Comparator: placebo	**Primary Outcome Measures:** Days of maintaining pregnancy **Secondary Outcome Measures:** 1. Presence or absence of achievement of 32 weeks of gestation 2. Presence or absence of achievement of 34 weeks of gestation 3. Presence or absence of achievement of 28 weeks of gestation in subjects enrolled in the period of less than 28 weeks of gestation 4. Change in AT activity 5. Change in PLT concentration 6. Change on D-dimer concentration 7. Change in FDP concentration 8. Sitting systolic blood pressure and sitting diastolic blood pressure 9. Proteinuria/creatinine ratio 10. Amount of blood lost during delivery 11. Biophysical Profile Score	June 2022	N=180	NCT04182373	JapicCTI-194997

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					12. Fetal growth rate 13. Apgar score 14. Presence or absence of neonatal asphyxia 15. Birth weight 16. Neonatal growth 17. Head and chest circumferences at birth 18. Short-term prognosis of neonates 19. The number of neonates who was hospitalized in the NICU 20. The number of days in the NICU 21. The number of neonates with respiratory management at the time of admission to the NICU 22. The number of days of respiratory management at the time of admission to the NICU				
KW-6356	P Ⅱ	Parkinson's Disease	JP	Randomized Parallel Assignment Double Blind - Experimental: KW-6356 Low Dose Oral	**Primary Outcome Measures:** Change from baseline in the Movement disorder society-unified Parkinson's disease rating scale(MDS-UPDRS) partⅢ score **Secondary Outcome Measures:**	December 8, 2017	N=175	NCT02939391	JapicCTI-163395

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				administration - Experimental: KW-6356 High Dose Oral administration - Placebo Comparator: Placebo Oral administration	1. CGI-I score 2. PGI-I score 3. Change from baseline in the PDQ-39 total scores 4. Number and percentage of subjects with treatment-emergent adverse events 5. Profiles of pharmacokinetics of plasma KHK6356 concentration 6. Change from baseline in the MDS-UPDRS subitem and total scores				
KW-6356	P Ⅰ	Parkinson's Disease	JP	Randomized Parallel Assignment Quadruple - Experimental: Part A-1 KW-6356 Low Dose - Experimental: Part A-2 KW-6356 Middle Dose - Experimental: Part A-3 KW-6356 High Dose - Experimental: Part B	**Primary Outcome Measures:** 1. Part A Number and percentage of subjects with treatment-emergent adverse events 2. Part B Number and percentage of subjects with treatment-emergent adverse events 3. Part C Profiles of pharmacokinetics of plasma KW-6356 concentrations **Secondary Outcome Measures:** 1. Part A Profiles of pharmacokinetics of plasma KW-6356 concentrations 2. Part B Profiles of pharmacokinetics of plasma	October 10, 2019	N=48	NCT03830528	

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				KW-6356 Multiple Dose - Experimental: Part C-1 KW-6356 Multiple Dose - Experimental: Part C-2 KW-6356 Multiple Dose - Placebo Comparator: Placebo	KW-6356 concentrations 3. Part C Number and percentage of subjects with treatment-emergent adverse events				
KW-6356	P Ⅱ b	Parkinson's Disease	JP	An interventional, multicenter, randomized, double-blind, placebo-controlled, parallel-group trial - Experimental: KW-6356 Low Dose - Experimental: KW-6356 High Dose	**Primary Outcome Measures:** Change from baseline in the Movement disorder society-unified Parkinson's disease rating scale (MDS-UPDRS) part III score **Secondary Outcome Measures:** Change from baseline in the total hours of awake time per day spent in the OFF stat	May 2020	N=502	NCT03703570	JapicCTI-184111

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				- Placebo Comparator: placebo					
KW-6356	P Ⅰ	Parkinson's Disease	JP	Single Group Assignment Open Label - Experimental: KW-6356/Healthy Japanese adult male subjects Period 1: intake of the index substrates at Day 1 (Cohort 1: midazolam, Cohort 2: caffeine + rosuvastatin) followed by Period 2: intake of KW-6356 at Day 4-13, intake of the index substrates at Day 11	**Primary Outcome Measures:** Geometric mean ratio of the major pharmacokinetic parameter (AUC0-t) of the index substrates in combination with or without KW-6356 **Secondary Outcome Measures:** 1. Cmax of the index substrates in combination with or without KW-6356 2. AUC0-∞ of the index substrates in combination with or without KW-6356 3. tmax of the index substrates 4. CL/F of the index substrates 5. Vz/F of the index substrates 6. t1/2 of the index substrates 7. Plasma concentrations of the index substrates 8. Plasma concentrations of KW-6356 9. Incidence of treatment-emergent adverse events	July 31, 2019	N=50	NCT03970798	

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
KW-6356	P Ⅰ	Hepatic Impairment	JP	Non-Randomized Parallel Assignment Open Label Single oral dose of KW-6356 - Experimental: Mild Hepatic Impairment -Experimental: Moderate Hepatic Impairment -Experimental: Healthy Subjects	**Primary Outcome Measures:** 1. Cmax 2. AUC0-t 3. AUC0-∞ 4. tmax 5. t1/2 6. CL/F 7. Vz/F **Secondary Outcome Measures:** 1. Plasma protein binding of KW-6356 and its major metabolite 2. Adverse Events 3. Clinical Laboratory Evaluations 4. Vital signs 5. 12-lead ECG 6. Physical examination	March 20, 2020	N=26	NCT04190654	
KW-6356	P Ⅰ	Parkinson's Disease	JP	Randomized Parallel Assignment Quadruple - Experimental:	**Primary Outcome Measures:** Change from baseline in QTc interval [QTcF] (ΔQTcF) **Secondary Outcome Measures:**	July 2020	N=128	NCT04342273	

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				KW-6356 therapeutic dose - Experimental: KW-6356 supratherapeutic dose - Placebo Comparator: Placebo - Active Comparator: Moxifloxacin	1. HR 2. QTc interval [QTcF] 3. PR interval 4. QRS interval 5. Placebo-corrected ΔQTcF 6. Placebo-corrected ΔHR 7. Placebo-corrected ΔPR interval 8. Placebo-corrected ΔQRS interval 9. Outliers in terms of category for HR 10. Outliers in terms of category for QTc interval (QTcF) 11. Outliers in terms of category for PR interval 12. Outliers in terms of category for QRS interval 13. Frequency of morphological changes in T wave 14. Frequency of morphological changes in U wave 15. Incidence of treatment-emergent adverse events 16. Plasma concentrations of KW-6356				

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
KW-6356	P Ⅰ	Parkinson's Disease	JP	Non-Randomized Single Group Assignment Open Label - Experimental: KW-6356 + Clarithromycin - Experimental: KW6356 + Rifampicin	**Primary Outcome Measures:** Geometric mean ratio of the pharmacokinetic parameter (AUC0-t) of KW-6356 in combination with or without a perpetrator drug **Secondary Outcome Measures:** 1. Cmax of KW-6356 in combination with or without a perpetrator drug 2. AUC0-∞ of KW-6356 in combination with or without a perpetrator drug 3. tmax of KW-6356 4. CL/F of KW-6356 5. Vz/F of KW-6356 6. t1/2 of KW-6356 7. Plasma concentrations of a perpetrator drug 8. Incidence of treatment-emergent adverse events	November 19, 2019	N=20	NCT04070495	
KW-6356	P Ⅰ	Healthy Male Subjects	US	Single Group Assignment Open Label	**Primary Outcome Measures:** 1. Cmax 2. tmax 3. AUC0-t 4. %AUCextra	October 2, 2019	N=8	NCT04147910	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				- Single oral dose of carbon-14-KW-6356.	5. t1/2 6. kel 7. Vz/F 8. CL/F 9. MRT 10. Whole blood/plasma concentration ratio 11. Aeurine 12. feurine 13. Aefeces 14. fefeces 15. Aetotal 16. fetotal 17. Metabolic profiling and identification (plasma, urine, and feces) **Secondary Outcome Measures:** 1. Adverse Events 2. Severe adverse events 3. Serum chemistry, hematology, and urinalysis 4. Vital signs 5. 12-lead ECG 6. Physical examination				

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
ME-401	P Ⅰ	Relapsed or Refractory Indolent B-cell Non-Hodgkin's Lymphoma	JP	Single Group Assignment Open Label - ME-401 administered orally	**Primary Outcome Measures:** Number of participants with treatment-emergent adverse events (TEAEs) **Secondary Outcome Measures:** 1. Plasma concentration level 2. Cmax 3. AUC 4. t1/2 5. OPR 6. DOR 7. PFS 8. TTR	September 30, 2021	N=12	NCT03985189	JapicCTI-194790
ME-401	P Ⅱ	Follicular Lymphoma (FL) Non-Hodgkin Lymphoma Marginal Zone Lymphoma	US, AU, EU Switzerland and KR, TW	Single Group Assignment open label	**Primary Outcome Measures:** Objective response rate (ORR) **Secondary Outcome Measures:** 1. DOR 2. CR 3. PFS 4. Overall Survival	December 2025	N=180	NCT03768505	

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Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					5. TEAEs 6. PK (Cmax)				
ME-401	P Ⅱ	Indolent B-cell Non-Hodgkin's Lymphoma	JP	Single Group Assignment Open Label - ME-401 administered orally	**Primary Outcome Measures:** Objective response rate (ORR) **Secondary Outcome Measures:** 1. DOR 2. PFS 3. CR 4. TTR 5. ORR 6. TEAEs 7. AESI 8. Plasma concentration level	September 2024	N=60	NCT04533581	JapicCTI-205449
RTA 402	P Ⅱ	Chronic Kidney Disease Type 2 Diabetes	JP	Randomized Parallel Assignment Double Blind - Experimental: bardoxolone methyl (RTA 402)	**Primary Outcome Measures:** 1. Number and types of adverse events 2. Change in GFR from baseline to 16 weeks **Secondary Outcome Measures:** 1. Change in eGFR from baseline to 16 weeks 2. Profiles of pharmacokinetics of plasma RTA 402 concentration	September 2017	N=216	NCT02316821	JapicCTI-142717

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				- Placebo Comparator: Placebo					
RTA 402	PⅢ	Diabetic Kidney Disease	JP	Randomized Parallel Assignment Double Blind - Experimental: bardoxolone methyl (RTA 402) - Placebo Comparator: Placebo	**Primary Outcome Measures:** Time to onset of a ≥ 30% decrease in eGFR from baseline or ESRD **Secondary Outcome Measures:** 1. Time to onset of a ≥ 40% decrease in eGFR from baseline or ESRD 2. Time to onset of a ≥ 53% decrease in eGFR from baseline or ESRD 3. Time to onset of ESRD 4. Change in eGFR from baseline at each evaluation time point	March 2022	N=1323	NCT03550443	JapicCTI-183955
RTA 402	PⅠ	Healthy Subject	JP	Randomized Crossover Assignment Open Label - Experimental: RTA 402 5mg 3cap at fasting	**Primary Outcome Measures:** 1. Cmax 2. AUC0-t **Secondary Outcome Measures:** 1. tmax 2. AUC0-∞ 3. t1/2	June 14, 2019	N=36	NCT04023903	JapicCTI-194865

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
				- Experimental: RTA 402 5mg 3cap after meal	4. MRT 5. kel				
RTA 402	P Ⅰ	Obese Adult Male	JP	Randomized Parallel Assignment Single - Experimental: RTA 402 5mg or 10mg oral administration - Placebo Comparator: Placebo	**Primary Outcome Measures:** 1. weight 2. fat mass 3. lean body mass 4. skeletal muscle mass index 5. waist 6. grip 7. visceral adipose tissue 8. abdominal subcutaneous adipose tissue 9. muscle mass 10. body fat mass 11. segmental muscle mass 12. total body water 13. extracellular water 14. basal metabolic rate	May 2020	N=18	NCT04018339	JapicCTI-194855
RTA 402	P Ⅱ	CKD patients with type 2 diabetes	JP	Randomized, open	**Primary Outcome Measures:** - Safety Adverse events - Efficacy glomerular filtration rate	December 1, 2013	N=40	NCT01574365	JapicCTI-121791 **Terminated**

主な開発品の治験概要（2020 年 12 月 31 日現在）

Drug Name	Trial Phase	Condition or disease	Country / region	Design	Endpoints	Study completion (Estimated)	Enrollment	Access to Clinical Trial Protocols	Remarks
					- Pharmacokinetics Plasma level of RTA 402				
RTA 402	P Ⅱ	CKD patients with type 2 diabetes	JP	Multi-center, open, single arm, exploratory study	**Primary Outcome Measures:** - Safety Adverse events - Efficacy glomerular filtration rate - Pharmacokinetics Plasma level of RTA 402	December 1, 2013	N=20	NCT01572610	JapicCTI-121792 **Terminated**