主な開発品の治験概要

2019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

Late-stage pipeline summary

Phase II

ASKP1240 (bleselumab)
Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients

KHK2375 (entinostat)
Breast cancer

KHK4083
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KRN125 (Pegfilgrastim)
Mobilization of hematopoietic stem cells into peripheral blood

KRN23 (burosumab)
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Phase III

AMG531 (romiplostim)
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KHK4827 (brodalumab)
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KHK4827 (brodalumab)
Palmoplantar Pustulosis

KHK7580 (evocalcet)
Secondary hyperparathyroidism

KRN23 (burosumab)
XLH (pediatric)

KW-0761 (mogamulizumab)
CTCL

KW-0761 (mogamulizumab)
HAM

KW-3357 (antithrombin gamma)
Preeclampsia

RTA 402 (bardoxolone methyl)
Diabetic kidney disease

AMG531 (romiplostim)

Aplastic anemia

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase II/III NCT02773290	Korea	Dec-20 N=46	AMG531 •sc, QW	•Primary endpoint: Proportion of subjects achieving a hematological response (any of the platelet response, erythroid response, and neutrophil response)	
Phase II/III NCT03957694	Japan, Korea, Taiwan	Mar-21 N=14	AMG531 •sc •Administered with anti-human thymocyte immunoglobulin (ATG) + ciclosporin A (CsA)	•Primary endpoint: Achievement of complete response (CR) or partial response (PR)	
Phase II/III NCT04095936	Japan, Korea,	Aug-21 N=24	AMG531 •sc •Administered with ciclosporin A (CsA)	•Primary endpoint: Achievement of complete response (CR) or partial response (PR)	

ASKP1240 (bleselumab)

Recurrence of focal segmental glomerulosclerosis (FSGS) in de novo kidney transplant recipients

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase II NCT02921789	U.S.	Apr-21 N=60	Arm 1: ASKP1240 •Basiliximab + Methylprednisone + Prednisone + ASKP1240 + Tacrolimus Arm 2 (Active Comparator): Standard of Care •Basiliximab induction + Tacrolimus + Methylprednisone + Prednisone + MMF	•Primary endpoint: Recurrence of FSGS at 3 months post-transplant •Secondary endpoint: Recurrence of FSGS, BRAR, efficacy failure, and biopsy-proven rFSGS at 12 months post-transplant	Jointly developed with Astellas

KHK2375 (entinostat)

Breast cancer

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase II NCT03291886	Japan	Nov-21 N=124	Arm 1 : KHK2375 + Exemestane KHK2375: 5mg, po, QW Exemestane: 25mg, po, QD Arm 2 : Placebo + Exemestane Placebo: po, QW Exemestane: 25mg, po, QD	•Primary endpoint: PFS •Secondary endpoint: OS, Antitumor effect	

KHK4083

Atopic dermatitis

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase II NCT03703102	North America, Europe, Japan,	Feb-21 N=250	Arm 1: KHK4083 •sc, dose level 1, dosing regimen 2 Arm 2: KHK4083 •sc, dose level 2, dosing regimen 1 Arm 1: KHK4083 •sc, dose level 3, dosing regimen 1 Arm 1: KHK4083 •sc, dose level 3, dosing regimen 2 Arm 2: Placebo •sc	•Primary endpoint: Percent change from baseline to Week 16 in EASI (Eczema Area and Severity Index) score	

KHK4827 (brodalumab)

Systemic sclerosis

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase III NCT03957681	Japan	Mar-23 N=100	Arm 1: KHK4827 •210mg, sc, Q2W Arm 2: Placebo •sc, Q2W	•Primary endpoint: Change in modified Rodnan skin score (mRSS)	

KHK4827 (brodalumab)

Palmoplantar Pustulosis

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase III NCT04061252	Japan	Mar-21 N=120	Arm 1: KHK4827 •210mg, sc, Q2W Arm 2: Placebo •sc, Q2W	•Primary endpoint: Change from baseline in Palmoplantar Pustulosis Area and Severity Index (PPPASI) total score at Week 16	

KHK7580 (evocalcet)

Secondary hyperparathyroidism

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase III NCT03822507	China Korea Taiwan Hong Kong	June-21 N=400	Arm 1: Experimental KHK7580 po Arm 2: Cinacalcet po	•Primary endpoint: Percent change in intact parathyroid hormone (PTH) level	

KRN125 (Pegfilgrastim)

Mobilization of hematopoietic stem cells into peripheral blood

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase II NCT03993639	Japan	Dec-20 N=41	KRN125 •Single dose, sc	•Primary endpoint: Achievement of >20 cells/μL positive for CD34 in peripheral blood from baseline to Day 7	

KRN23 (burosumab)

XLH (pediatric)

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase III NCT03233126	Japan	Mar-20 N=10	KRN23 •sc, Q2W, 86 weeks	•Primary endpoint: AE •Secondary endpoint: Laboratory values, Change in Serum P, $1,25(OH)_2D$ (1,25-dihydroxyvitamin D), Rickets Severity Score (RSS) total score, Six Minute Walk Test, PK and so on	

KRN23 (burosumab)

TIO/ENS

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase II NCT02304367	U.S.	Jan-21 N=17	KRN23 •sc, starting dose of 0.3 mg/kg, Q4W. Doses may be titrated up to a maximum of 2.0 mg/kg, Q2W.	•Primary endpoint: The proportion of subjects achieving mean serum P levels above the lower limit of normal, Percent change from baseline in excess osteoid based on analysis of iliac crest bone biopsies after 48 weeks of KRN23 treatment •Secondary endpoint: AE, PK, PD, bone turnover biomarkers (ex.BALP, CTx, P1NP), osteocalcin, BFI (Brief Fatigue Inventory), BPI and so on	Jointly developed with Ultragenyx (U.S.)
Phase II NCT02722798	Japan, Korea	Dec-20 N=6	KRN23 Q4W •sc, 44 weeks	•Primary endpoint: Serum P concentration •Secondary endpoint: PK, PD, Evaluate changes in skeletal disease/osteomalacia and so on	

KW-0761 (mogamulizumab)

Hematological cancer - relapsed/refractory CTCL

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase III NCT01728805	U.S., Europe, Japan, others	Dec-20 N=372	Arm 1: KW-0761 •1.0 mg/kg QW x 4 in cycle 1 then Q2W until progression Arm 2: Vorinostat •400 mg, po, QD	•Primary endpoint: PFS •Secondary endpoint: ORR	

KW-0761 (mogamulizumab)

HTLV-1 associated myelopathy (HAM)

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase III NCT03191526	Japan	Dec-20 N=66	Arm 1: KW-0761 Q12W iv, 0.3mg/kg, double-blind, after that open study for 24 weeks Arm 2: Placebo Q12W Iv, double-blind, after that open study for 24 weeks	•Primary endpoint: Improvement in Osame's motor disability score •Secondary endpoint: HTLV-1 Proviral load in peripheral blood, Mean of twice 10 m walking time, Modified Ashworth Scale	

KW-3357 (antithrombin gamma)

Preeclampsia

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase III NCT04182373	Japan	June-22 N=180	Arm 1: KW-3357 Intravenous infusion, once a day, 7 days Arm 2: Placebo Intravenous infusion, once a day, 7 days	•Primary endpoint: Days of maintaining pregnancy	

KW-6356

Parkinson's disease

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase II NCT03703570	Japan	May-20 N=502	Arm 1: KW-6356 •Low dose, po Arm 2: KW-6356 •High dose, po Arm 3: Placebo, po	•Primary endpoint: Change from baseline in the Movement disorder society-unified Parkinson's disease rating scale(MDS-UPDRS) part III score •Secondary endpoint: Change from baseline in the total hours of awake time per day spent in the OFF state.	

RTA 402 (bardoxolone methyl)

Diabetic kidney disease

Trial phase	Country/ region	Estimated study completion date / enrollment	Design	Endpoints	Remarks
Phase III AYAME NCT03550443	Japan	Mar-22 N=1323	Arm 1: RTA 402 •5, 10, or 15 mg, po, QD Arm 2: Placebo •po, QD	•Primary endpoint: Time to onset of a ≥ 30% decrease in eGFR (estimated GFR) from baseline or end-stage renal disease (ESRD)	