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ADISINSIGHT REPORT

Stapokibart: First Approval

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Abstract

Stapokibart (Kangyueda®; 康悦达®) is a humanised IgG4 monoclonal antibody targeted against the interleukin (IL)-4 receptor alpha subunit (IL-4Rα). By binding IL-4Rα, stapokibart blocks the binding by (and subsequent signalling of) IL-4 and IL-13, two type 2 cytokines. Stapokibart is being developed by KeyMed Biosciences for the treatment of atopic dermatitis and other type 2 inflammatory diseases. In September 2024, stapokibart received its first approval, in China, for use in the treatment of moderate-to-severe atopic dermatitis in adults whose disease is poorly controlled by, or not suitable for, topical medications. Subsequently, stapokibart additionally received approval in China for use in the treatment of chronic rhinosinusitis with nasal polyps (December 2024) and for the treatment of seasonal allergic rhinitis (February 2025). Stapokibart is also under clinical evaluation for use in the treatment of moderate-to-severe asthma and chronic obstructive pulmonary disease, and prurigo nodularis. This article summarises the milestones in the development of stapokibart leading to this first approval for moderate-to-severe atopic dermatitis.

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Stapokibart (Kangyueda®; 康悦达®): Key Points

An IL-4Rα antagonist is being developed by KeyMed Biosciences for the treatment of atopic dermatitis and other type 2 inflammatory diseases

Received its first approval on 10 September 2024, in China

Approved for use in moderate-to-severe atopic dermatitis in adults whose disease is poorly controlled by, or not suitable for, topical medications; and in the treatment of chronic rhinosinusitis with nasal polyps; and the treatment of seasonal allergic rhinitis

This profile has been extracted and modified from the *AdisInsight* database. *AdisInsight* tracks drug development worldwide through the entire development process, from discovery, through pre-clinical and clinical studies to market launch and beyond.

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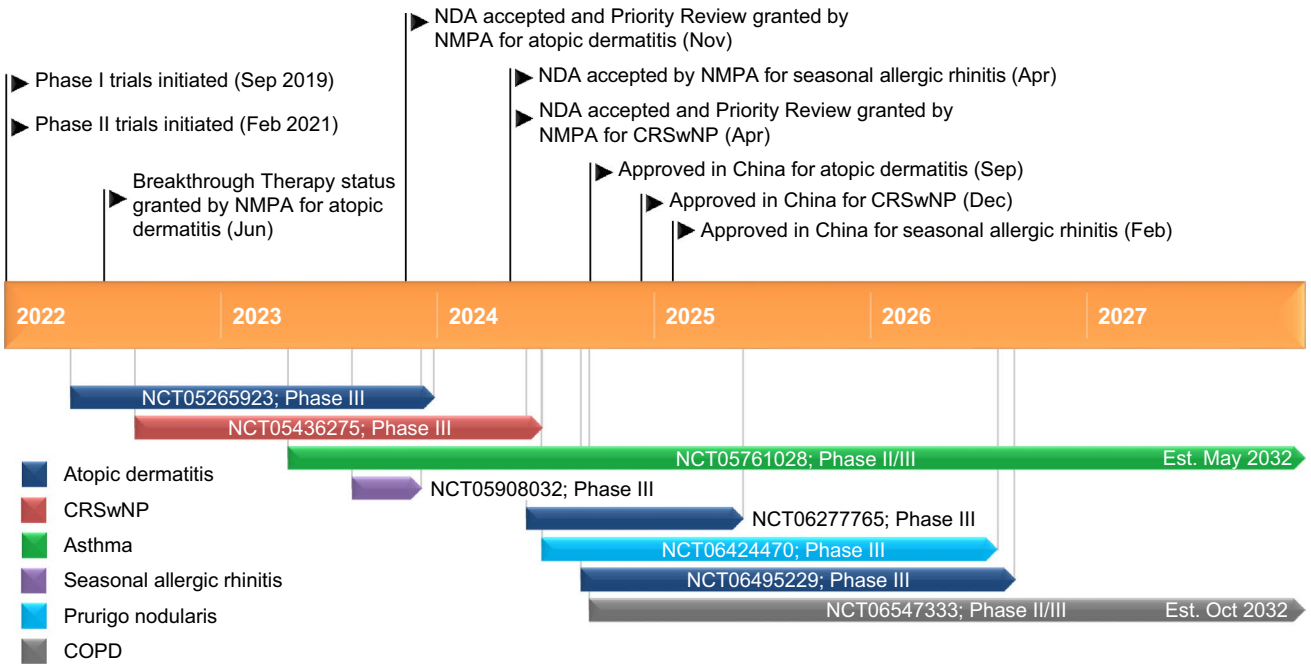
1 Introduction

The interleukin (IL)-4 receptor alpha subunit (IL-4Rα) is established as a valuable therapeutic target for the treatment of type 2 inflammatory diseases [1, 2], with the IL-4Rα antagonist dupilumab approved in the USA [3] and the EU [4] for use in the treatment of a range of atopic and allergic diseases. Like dupilumab, stapokibart (Kangyueda®; 康悦达®) is an IgG4 monoclonal antibody targeted against IL-4Rα [5, 6]. The binding of stapokibart to IL-4Rα blocks the binding by (and subsequent signalling of) IL-4 and IL-13, two type 2 cytokines. Stapokibart is being developed by KeyMed Biosciences for the treatment of atopic dermatitis and other type 2 inflammatory diseases. In September 2024, stapokibart received its first approval, in China, for use in the treatment of moderate-to-severe atopic dermatitis in adults whose disease is poorly controlled by, or not suitable for, topical medications [5, 7]. Subsequently, stapokibart received approval in China in December 2024 for use in the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) [8] and in February 2025 for the treatment of seasonal allergic rhinitis [9].

Stapokibart is to be administered by subcutaneous injection into the thigh, abdomen (excluding the area within 5 cm of the navel) or upper arm [5]. Tender, damaged, bruised or scarred areas of skin should be avoided. The recommended dosage in the treatment of moderate-to-severe atopic dermatitis is a loading dose of 600 mg (two 300-mg injections at different sites) followed by 300 mg every other week, with



Key milestones in the development of stapokibart. *COPD* chronic obstructive pulmonary disease, *CRSwNP* chronic rhinosinusitis with nasal polyps, *Est.* estimated, *NDA* New Drug Application, *NMPA* National Medical Products Administration (China)

rotation of the injection site. No dose adjustment is required for patients with mild or moderate renal impairment. No data are available on the use of stapokibart in patients with severe renal impairment or end-stage renal disease or with hepatic impairment. For elderly patients, it is recommended that stapokibart is used under the guidance of a clinician. Discontinuation of stapokibart therapy should be considered in patients with atopic dermatitis with no response after 16 weeks of treatment; patients with a partial response may experience further improvement in their condition with ongoing treatment after 16 weeks [5].

Stapokibart was granted Breakthrough Therapy status by the National Medical Products Administration (NMPA) in China for atopic dermatitis in June 2022 [10], with Priority Review granted in this indication in November 2023 [11]. New Drug Applications for stapokibart were accepted by the NMPA for CRSwNP [8] and seasonal allergic rhinitis [12] in April 2024, with Priority Review granted for the former [8]. Stapokibart is also under clinical evaluation for use in the treatment of moderate-to-severe asthma and chronic obstructive pulmonary disease (COPD), and prurigo nodularis.

2 Scientific Summary

Stapokibart is a humanised IgG4 monoclonal that selectively binds IL-4Rα [5, 6]. It is expressed in Chinese hamster ovary cells using recombinant DNA technology [5].

2.1 Pharmacodynamics

Stapokibart is an IL-4Rα antagonist [5, 6]. Binding of stapokibart to IL-4Rα inhibits both IL-4 and IL-13 binding, thereby inhibiting the activation of downstream signalling pathways and the release of proinflammatory cytokines. In clinical trials in patients with atopic dermatitis [13–15], seasonal allergic rhinitis [16] or CRSwNP [17], stapokibart suppressed levels of key type 2-associated biomarkers, including serum thymus and activation-regulated chemokine (TARC) and total IgE [13–17]; stapokibart also reduced levels of lactate dehydrogenase (LDH) [13, 14], a biomarker for atopic dermatitis disease severity [18]. In adults with atopic dermatitis receiving subcutaneous stapokibart 300 mg once every 2 weeks (with a 600-mg loading dose on day 1), mean changes from baseline in serum total IgE and LDH at week 16 were − 50.6% and − 19.8%, respectively [5].

2.2 Pharmacokinetics

Subcutaneous stapokibart exhibits non-linear pharmacokinetics, with greater than dose-proportional increases in exposure over the dose range of 75–600 mg [15]. Following a single dose of stapokibart over the dose range of 75–600 mg in healthy subjects, peak plasma concentrations are reached in a median of 3–7 days; the mean apparent volume of distribution in each dose group ranged from 3.64 L to 6.73 L [15]. In patients with atopic dermatitis administered a loading dose of stapokibart 600 mg followed by stapokibart 300 mg every 2 weeks, plasma concentrations approach steady state at 12 weeks [5].

Features and properties of stapokibart

Alternative names	Anti-IL-4Rα recombinant fully humanised antibody - KeyMed Biosciences; CM-310; CM310 recombinant humanised monoclonal antibody injection; IL-4Rα(mAb) - KeyMed Biosciences; Kangyueda®; 康悦达®
Class	Anti-inflammatories; anti-allergics; anti-asthmatics; monoclonal antibodies; skin disorder therapies
Mechanism of action	IL-4Rα antagonism
Route of administration	Subcutaneous injection
Pharmacodynamics	Selectively binds IL-4Rα, blocking IL-4 and IL-13 and thereby inhibiting the activation of downstream signalling pathways and the release of proinflammatory cytokines; suppresses levels of type 2-associated biomarkers, including serum TARC and total IgE
Pharmacokinetics	Non-linear pharmacokinetics, with greater than dose-proportional increases in exposure over the dose range of 75–600 mg; median T_{max} = 3–7 days; mean apparent V_D = 3.64–6.73 L; mean apparent clearance = 0.0246 L/h; mean elimination half-life = 12.9 days
Most common adverse events	Conjunctivitis, injection-site reactions, joint pain and eye dryness
ATC codes	
WHO ATC codes	D04A-X (Other antipruritics); D11 (Other dermatological preparations); R03 (Drugs for obstructive airway diseases)
EphMRA ATC codes	D11 (Other dermatological preparations); D4A (Antipruritics, including topical antihistamines, anaesthetics, etc); R3 (Anti-asthma and COPD products)

COPD chronic obstructive pulmonary disease, *IL-4Rα* interleukin 4 receptor alpha subunit, *TARC* thymus and activation-regulated chemokine, T_{max} time to peak plasma concentration, V_D volume of distribution

Although the specific pathways have not been characterised, stapokibart is expected to undergo catabolism to small peptides and amino acids in the same manner as endogenous IgG [5]. With lower plasma drug concentrations, elimination of stapokibart mainly occurs via IL-4Rα target mediated elimination, whereas elimination via proteolysis is dominant with higher drug concentrations. Following multiple doses of stapokibart in adults with atopic dermatitis, the mean apparent clearance was 0.0246 L/h and the mean elimination half-life was 12.9 days [5].

Gender and age have no clinically relevant effects on exposure to stapokibart based on population pharmacokinetic analyses [5]. Although lower trough concentrations of stapokibart are observed with increasing body weight, there are no clinically significant effects of body weight on stapokibart efficacy. Stapokibart is expected to have a low potential for clinically relevant pharmacokinetic drug-drug interactions [5].

2.3 Therapeutic Trials

2.3.1 Atopic Dermatitis

Stapokibart improved signs and symptoms of atopic dermatitis in adults with moderate-to-severe disease in the pivotal, multicentre, randomised, double-blind, placebo-controlled phase III trial (NCT05265923) [14]. In the trial, 500 adults with moderate-to-severe atopic dermatitis were enrolled at 59 centres in China and randomised (1 : 1) to receive subcutaneous stapokibart 300 mg (with a 600-mg loading dose on day 1) ($n = 251$) or placebo ($n = 249$) every 2 weeks. The trial included a 16-week double-blind period, followed by a 36-week maintenance period and an 8-week follow-up period. At week 16, significantly more stapokibart recipients than placebo recipients achieved a ≥ 75% improvement from baseline in Eczema Area and Severity Index (EASI) score (EASI-75 response; 66.9% vs 25.8%; $p < 0.0001$) and an Investigator's Global Assessment (IGA) score of 0 or 1 and a ≥ 2-point reduction from baseline (IGA response; 44.2% vs 16.1%; $p < 0.0001$) [co-primary endpoints]. Stapokibart was also associated with significant ($p < 0.0001$) improvements compared with placebo in all secondary efficacy endpoints, including EASI-50 (82.5% vs 43.1%) and EASI-90 (37.1% vs 11.3%) response rates, and least-squares mean (LSM) reductions from baseline in body surface area (BSA) affected by atopic dermatitis (69.2% vs 29.4%), EASI score (74.3% vs 33.6%) and weekly average of daily peak pruritus numerical rating scale (PP-NRS) score (42.1% vs 14.9%), all at week 16 [14].

The clinical benefits of stapokibart observed at week 16 were sustained with ongoing treatment to week 52 [5, 19]. Among evaluable patients in the stapokibart group who received at least one dose of stapokibart in the maintenance period ($n = 237$), 99.1% had an EASI-50 response, 92.5% had an EASI-75 response, 77.1% had an EASI-90 response and 67.3% had an IGA response at week 52 [5, 19].

Inclusion criteria for the trial were a duration of atopic dermatitis for ≥ 12 months before screening, ≥ 10% BSA

involvement, an EASI score ≥ 16, an IGA score ≥ 3 and a PP-NRS average score ≥ 4 [5]. At baseline, patients had a mean age of 39.9 years, a mean duration of disease of 9.6 years, a mean of 36.8% BSA involvement, a mean EASI score of 24.45 and a mean weekly average of daily PP-NRS score of 7.22; 52.4% of patients had an IGA score of 3 and 47.6% had an IGA score of 4 [14].

The efficacy of stapokibart in the treatment of moderate-to-severe atopic dermatitis in adults was earlier demonstrated in a 16-week, randomised, double-blind, placebo-controlled phase IIb trial (NCT04805411) [13]. Patients who completed NCT04805411 or an earlier phase I/IIa dose-escalation trial (NCT04893941 [15]) were invited to enrol in a multicentre, long-term, open-label extension (OLE) phase II trial (NCT04893707) [20]. Patients in the OLE trial ($n = 127$) received a stapokibart 600-mg loading dose followed by stapokibart 300 mg every 2 weeks up to 52 weeks. At week 52, EASI-50, EASI-75 and EASI-90 response rates were 96.3%, 87.9% and 71.0%, respectively, with 58.9% of patients achieving an IGA response [20].

2.3.2 Seasonal Allergic Rhinitis

Stapokibart as an add-on to standard-of-care treatment demonstrated efficacy in adults with uncontrolled seasonal allergic rhinitis in the multicentre, randomised, double-blind, placebo-controlled, phase III PHECDA trial (NCT05908032) [12]. Stapokibart significantly improved the mean change from baseline in daily reflective total nasal symptom scores (TNSS) over 2 weeks of treatment compared with placebo (primary endpoint). The TNSS is the sum of the four symptom scores for rhinorrhoea, nasal congestion, nasal itching and sneezing, where each symptom is scored on a scale of 0 to 3.

An earlier randomised, double-blind, placebo-controlled phase II trial (NCT05470647) provided some evidence for the efficacy of stapokibart in the treatment of seasonal allergic rhinitis, although failing to meet its primary endpoint [16]. In the phase II trial, 92 patients with uncontrolled seasonal allergic rhinitis were enrolled from four centres in China and randomised (1 : 1: 1) to receive subcutaneous stapokibart 300 mg (with a 600-mg loading dose on day 1) once weekly ($n = 31$) or once every 2 weeks ($n = 30$), or placebo once weekly ($n = 31$), for 4 weeks. All patients additionally received mometasone furoate nasal spray 100 µg once daily per nostril and oral loratadine 10 mg once daily. The trial included a 4-week double-blind treatment period during the fall pollen season, followed by an 8-week follow-up period.

In the phase II trial, stapokibart once weekly or once every 2 weeks failed to significantly improve daily reflective TNSS over 2 weeks of treatment [primary endpoint; LSM differences compared with placebo of − 0.2 in the stapokibart once weekly group ($p = 0.67$) and − 1.0 in the stapokibart once every 2 weeks group ($p = 0.065$)] [16]. Significant improvements were observed with stapokibart once every 2 weeks compared with placebo in several secondary endpoints, including the mean percentage change from baseline in daily reflective TNSS over 2 weeks of treatment (LSM difference of − 12.9%; $p = 0.043$) and the mean percentage change in morning instantaneous TNSS over 2 weeks (LSM difference of − 17.4%; $p = 0.013$) and 4 weeks (LSM difference of − 15.4%; $p = 0.026$) of treatment, although secondary endpoints were not adjusted for multiplicity.

2.3.3 Chronic Rhinosinusitis with Nasal Polyps

Stapokibart as an add-on to standard-of-care treatment reduced nasal polyp size and alleviated nasal congestion in adults with uncontrolled CRSwNP in the multicentre, randomised, double-blind, placebo-controlled, phase III CROWNS-2 trial (NCT05436275) [11, 21]. In CROWNS-2, 180 adults with bilateral CRSwNP were enrolled and randomised (1 : 1) to receive subcutaneous stapokibart 300 mg or placebo every 2 weeks [11]. All patients additionally received mometasone furoate nasal spray 100 µg once daily per nostril [21]. The trial included a 24-week double-blind period, followed by a 28-week maintenance period (with all patients to receive stapokibart 300 mg every 2 weeks) and an 8-week follow-up period [21]. Stapokibart was associated with significant ($p < 0.0001$) improvements from baseline both in nasal polyp score (NPS) and nasal congestion score (NCS) at week 24 (co-primary endpoints) compared with placebo, based on a preliminary analysis [11].

Earlier, stapokibart as an add-on to standard-of-care treatment demonstrated efficacy in the multicentre, randomised, double-blind, placebo-controlled, phase II CROWNS-1 trial (NCT04805398) in patients with severe eosinophilic CRSwNP [17]. In CROWN-1, 56 adults with severe eosinophilic CRSwNP were enrolled and randomised (1 : 1) to receive subcutaneous stapokibart 300 mg or placebo for 16 weeks, followed by 8 weeks of follow-up. All patients additionally received mometasone furoate nasal spray 100 µg once daily per nostril throughout the trial. At week 16, stapokibart was associated with significant improvements from baseline both in NPS and NCS (co-primary endpoints) compared with placebo (LSM differences for stapokibart vs placebo of − 2.1 and − 0.9, respectively; $p < 0.0001$ for both). Stapokibart was also associated with significant benefits compared with placebo in all secondary efficacy endpoints, including change from baseline at week 16 in the sinus Lund-Mackay CT score, the total symptom score (TSS), the University of Pennsylvania Smell Identification Test (UPSIT) score and the 22-item Sino-Nasal Outcome Test (SNOT-22) score [17].

Key clinical trials of stapokibart (KeyMed Biosciences)

Identifier	Indication	Phase	Drug(s)	Status
NCT05265923	Atopic dermatitis	III	Stapokibart; placebo	Completed
NCT06277765	Atopic dermatitis	III	Stapokibart; placebo	Not yet recruiting
NCT06495229	Atopic dermatitis	III	Stapokibart	Not yet recruiting
NCT04805411	Atopic dermatitis	II	Stapokibart; placebo	Completed
NCT05715320	Atopic dermatitis	II	Stapokibart	Completed
NCT04893707	Atopic dermatitis	II	Stapokibart	Completed
NCT05579925	Atopic dermatitis	II	Stapokibart	Completed
NCT06116565	Atopic dermatitis	II	Stapokibart	Not yet recruiting
NCT04893941	Atopic dermatitis	I/II	Stapokibart; placebo	Completed
NCT06162507	Atopic dermatitis	I/II	Stapokibart	Completed
NCT05908032	Seasonal allergic rhinitis	III	Stapokibart; placebo	Completed
NCT05908721	Seasonal allergic rhinitis	II	Stapokibart	Completed
NCT06171074	Seasonal allergic rhinitis	II	Stapokibart	Not yet recruiting
NCT05436275	CRSwNP	III	Stapokibart; placebo	Completed
NCT04805398	CRSwNP	II	Stapokibart; placebo	Completed
NCT05131464	CRSwNP	II	Stapokibart	Completed
NCT06424470	Prurigo nodularis	III	Stapokibart; placebo	Not yet recruiting
NCT05186909	Asthma	II	Stapokibart; placebo	Completed

CRSwNP chronic rhinosinusitis with nasal polyps

2.4 Adverse Events

In the 16-week double-blind period of the pivotal phase III trial in patients with moderate-to-severe atopic dermatitis (NCT05265923), treatment-emergent adverse events (TEAEs) occurred with a similar incidence between the stapokibart (71.3%) and placebo (66.3%) groups [14]. Most TEAEs were of mild or moderate severity. Drug-related TEAEs also occurred with a similar incidence between the stapokibart (19.9%) and placebo (16.1%) groups. Serious TEAEs were reported in three patients (1.2%) in each group; no serious TEAEs in the trial were considered to be related to study treatment. Two patients (0.8%) in the stapokibart group and one patient (0.4%) in the placebo group experienced TEAEs leading to treatment discontinuation [14].

Across four clinical trials in patients with atopic dermatitis, the most common adverse reactions with stapokibart were conjunctivitis and injection-site reactions [5]. Most cases of conjunctivitis and keratitis resolved without discontinuation of stapokibart therapy [5, 19]. Other common adverse reactions (incidence ≥ 1/100 to < 1/10) in patients with atopic dermatitis receiving stapokibart were joint pain and eye dryness [5]. No new safety signals were identified with longer-term stapokibart therapy (up to 52 weeks) [5, 19, 20].

Based on currently available data, stapokibart is also generally well tolerated in adults with seasonal allergic rhinitis [16] or CRSwNP [21], with similar incidences of TEAEs observed between stapokibart and placebo recipients in clinical trials.

2.5 Ongoing Clinical Trials

A multicentre, open-label phase II trial (NCT06116565) is planned to further evaluate the long-term safety and efficacy of stapokibart in adults with moderate-to-severe atopic dermatitis. Additionally, two multicentre phase III trials are planned to evaluate the safety and efficacy of stapokibart in adolescents (aged 12–18 years) with moderate-to-severe atopic dermatitis: a single-arm, open-label trial (NCT06495229); and a randomised, double-blind, placebo-controlled trial (NCT06277765).

The efficacy, safety, immunogenicity, pharmacokinetics and pharmacodynamic effects of stapokibart in patients aged 12–75 years with moderate-to-severe asthma are being evaluated in a 52-week, multicentre, randomised, double-blind, placebo-controlled phase II/III trial (NCT05761028). Additionally, multicentre, randomised, double-blind, placebo-controlled clinical trials are planned to evaluate the efficacy, safety, immunogenicity, pharmacokinetics and pharmacodynamic effects of stapokibart in adults with prurigo nodularis (phase III; NCT06424470) and moderate-to-severe COPD (phase II/III; NCT06547333).

3 Current Status

Stapokibart received its first approval on 10 September 2024, in China, for the treatment of moderate-to-severe atopic dermatitis in adults whose disease is poorly controlled by, or not suitable for, topical medications [5, 7]. Subsequently, stapokibart received approval in China on 23 December 2024 for the treatment of CRSwNP [8] and on 07 February 2025 for the treatment of seasonal allergic rhinitis [9].

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Declarations

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Ethics Approval, Consent to Participate, Consent to Publish, Availability of Data and Material, Code Availability Not applicable.

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