ROCKET shuttle

A phase 3, randomized, placebo-controlled study assessing the efficacy, safety, and tolerability of rocatinlimab in combination with topical therapies in adults with moderate-to-severe atopic dermatitis (ROCKET-Shuttle)[1]

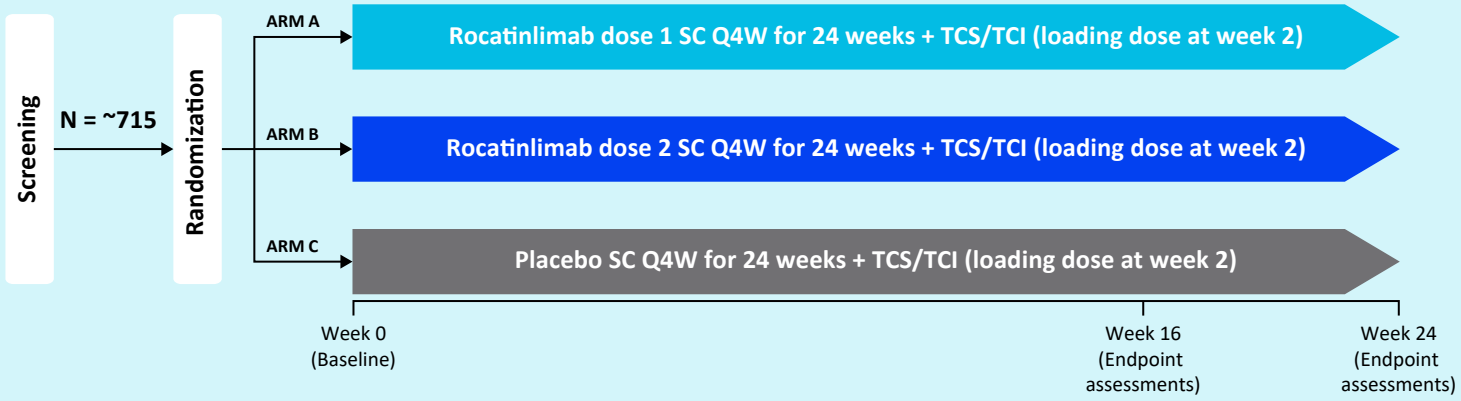
Rocatinlimab is an anti-OX40 monoclonal antibody that inhibits and reduces the number of OX40+ pathogenic T cells[2,3]

Objective:[1]
Assess the efficacy, safety, and tolerability of rocatinlimab in adult subjects with moderate-to-severe AD

Patient Population:[1]
Adults with moderate-to-severe AD with inadequate response to TCS of medium/high potency within 6 months ± TCI

Primary Endpoints:[1]
- vIGA-AD™ score of 0 or 1 with ≥ 2-point reduction from baseline at week 24
- EASI 75 at week 24

Study Schema[1]



Key Secondary Endpoints:[1]
- EASI 75 at week 16 and EASI 90 at week 24
- vIGA-AD™ score of 0 or 1 at week 16
- ≥ 4-point reduction from baseline in the weekly average of daily worst pruritus NRS score at weeks 16 and 24
- Change from baseline in the weekly average of daily AD skin pain NRS score at week 24
- vIGA-AD™ score of 0 or 1 and presence of barely perceptible erythema/no erythema at week 24

Inclusion Criteria:[1]
- ≥ 18 years of age with a diagnosis of AD for ≥ 6 months
- Inadequate response to TCS of medium/high potency within 6 months ± TCI
- EASI ≥ 16
- vIGA-AD™ score ≥ 3
- ≥ 10% BSA of AD involvement
- Worst pruritus NRS ≥ 4

Exclusion Criteria:[1]
- Treatment with a biological product within 12 weeks or 5 half-lives prior to day 1
- Treatment with any of the following within 4 weeks or 5 half-lives prior to day 1: systemic corticosteroids, systemic immunosuppressants, JAKi, phototherapy
- Treatment with any of the following within 1 week prior to day 1: TCS; TCI; antipruritic drug; topical PDE4i; other topical immunosuppressive agents; or a combination of topical agents including TCS, TCI, PDE4i, or other topical immunosuppresive agents

Products under investigational study have not been approved by any regulatory authority.

NCT05724199

EudraCT: 2022-000930-41

AD, atopic dermatitis; BSA, body surface area; EASI, Eczema Area and Severity Index; EASI 75/90, achievement of ≥ 75%/90% reduction from baseline in Eczema Area and Severity Index score; JAKi, Janus kinase inhibitor; NRS, numerical rating scale; PDE4i, phosphodiesterase-4 inhibitor; Q4W, once every 4 weeks; SC, subcutaneous; TCI, topical calcineurin inhibitor; TCS, topical corticosteroid; vIGA-AD™, Validated Investigator Global Assessment for Atopic Dermatitis.

References: 1. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05724199. Accessed February 28, 2023.
2. Amgen Pipeline. https://www.amgenpipeline.com/. Accessed January 10, 2023.
3. Nakagawa H, et al. *J Dermatol Sci.* 2020;99:82-89.

Rocatinlimab (AMG 451) is being developed in collaboration with Kyowa Kirin Co., Ltd., where it was identified as KHK4083.

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AMGEN KYOWA KIRIN