

News release

Kyowa Kirin to Present Atopic Dermatitis Clinical Data from KHK4083/AMG 451 Phase 2 Study at The European Academy of Dermatology and Venereology 30th Congress

TOKYO, Japan, 13 September, 2021 – Kyowa Kirin Co., Ltd. (TSE:4151, President and CEO: Masashi Miyamoto, “Kyowa Kirin”) , a global specialty pharmaceutical company creating innovative medical solutions utilizing the latest biotechnology, today announced detailed data from a Phase 2 study of KHK4083/AMG 451 will be highlighted in late-breaking oral presentation at the European Academy of Dermatology and Venereology 30th Virtual Congress to be held September 29 – October 2, 2021. KHK4083/AMG 451 is a potential first-in-class anti-OX40 fully human monoclonal antibody in development for the treatment of atopic dermatitis, with potential in other autoimmune diseases.

Presentation Title:

Efficacy and safety results of KHK4083/AMG 451 (anti-OX40 mAb) in subjects with moderate to severe atopic dermatitis: a phase 2, multicentre, randomized, double-blind, parallel-group, placebo-controlled study

Submission Topic: 5. Atopic Dermatitis/Eczema

Session date and time: Saturday 2 October 2021, 10.00 - 11.00(CEST)

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The abstract will be available on the EADV Congress website.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

About KHK4083/AMG 451

KHK4083/AMG 451 is an anti-OX40 fully human monoclonal antibody engineered with Kyowa Kirin's patented POTELLIGENT® defucosylation technology to enhance its antibody-dependent cellular cytotoxicity (ADCC) activity. The initial KHK4083/AMG 451 antibody was discovered in collaboration between Kyowa Kirin US Research and La Jolla Institute for Immunology.

KHK4083/AMG 451 targets and inhibits the activity of the OX40 receptor expressed on the surface of effector T-cells, and has been shown to deplete activated OX40⁺ T-cells by ADCC. It has been reported that effector T cells expressing OX40 are present in the lesions of patients with atopic dermatitis and are critical in their development. Kyowa Kirin antibodies powered by POTELLIGENT technology with ADCC activity are currently marketed in several other therapeutic areas, including Oncology and Asthma. This potent antibody-enhancement platform is also licensed to numerous third parties throughout the biopharmaceutical industry.

On June 1, 2021, Kyowa Kirin entered into an agreement with Amgen (NASDAQ: AMGN) to jointly develop and commercialize KHK4083/AMG 451. Under the terms of the agreement, Amgen will lead the development, manufacturing, and commercialization for KHK4083/AMG 451 for all markets globally, except Japan, where Kyowa Kirin will retain all rights. If approved, the companies will co-commercialize the asset in the United States and Kyowa Kirin has opt-in rights to co-promote in certain other markets including Europe and Asia.

An overview of the KHK4083/AMG 451 Phase 2 Study

A Phase 2, multicenter, randomized, double-blind, and placebo-controlled clinical study ([NCT03703102](https://clinicaltrials.gov/ct2/show/study/NCT03703102)) was conducted in the U.S., Japan, Canada, and Germany to investigate the efficacy and safety of KHK4083/AMG 451. The study included 274 patients with moderate-to-severe atopic dermatitis, who were not adequately controlled with topical agents. The primary endpoint of the study was "percent change from baseline in Eczema Area and Severity Index (EASI) ¹ at 16 weeks".

About OX40

OX40 is a co-stimulatory molecule and a member of the tumor necrosis factor receptor (TNFR) superfamily. It has been reported that activated effector T cells express OX40^{2,3} and are present in the lesions of patients with atopic dermatitis⁴. Professor Michael Croft, Ph.D., who is Director, Scientific Affairs, La Jolla Institute for Immunology helped identify that OX40 plays an important role in T cell proliferation, survival and formation of memory T cells⁵.

About Kyowa Kirin

Kyowa Kirin strives to create and deliver novel medicines with life-changing value. As a Japan-based Global Specialty Pharmaceutical Company with a more than 70-year heritage, we apply cutting-edge science including expertise in antibody research and engineering, to address the needs of patients and society across multiple therapeutic areas including Nephrology, Oncology,

Immunology/Allergy and Neurology. Across our four regions – Japan, Asia Pacific, North America and EMEA/International – we focus on our purpose, to make people smile, and are united by our shared values of commitment to life, teamwork/Wa, innovation, and integrity. You can learn more about the business of Kyowa Kirin at: <https://www.kyowakirin.com/>.

Kyowa Kirin International is a subsidiary of Kyowa Kirin Co., Ltd.

References

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