

Kyowa Hakko Kirin Enters New Development and Commercialisation Agreements with AstraZeneca for All Benralizumab Indications beyond COPD and Asthma in Asia Inclusive of Japan

Tokyo, Japan, March 25, 2019—Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Masashi Miyamoto, “Kyowa Hakko Kirin”) announces that the company has entered new agreements with AstraZeneca granting AstraZeneca exclusive rights to benralizumab (brand name “Fasenra”) for all additional indications in Asia inclusive of Japan. Under previous agreements, AstraZeneca currently has the rights to benralizumab in the countries and regions for chronic obstructive pulmonary disease (COPD) and asthma indications; AstraZeneca now has global rights to benralizumab for all current and future indications.

Under the terms of the agreements, AstraZeneca will pay Kyowa Hakko Kirin up-front and subsequent payments for regulatory and commercial milestones. Other financial terms are the same as previous agreements between the companies. AstraZeneca will now also be responsible for development, sales and marketing of benralizumab for all indications in 14 Asian countries and regions including Japan.

“We are pleased to enter these agreements with our partner AstraZeneca, a global biopharmaceutical company with strong development and commercial functions,” said Wataru Murata, Executive Officer, Director of Corporate Strategy & Planning Department of Kyowa Hakko Kirin. “Through AstraZeneca’s solid global network, we hope this innovative product contributes more and more patients all over the world.”

Benralizumab is now approved as an add-on maintenance treatment in severe, eosinophilic asthma in the US, EU, Japan, and several other jurisdictions, with further regulatory reviews ongoing.

The Kyowa Hakko 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 bernalizumab (Brand Name: Fasenra® subcutaneous injection 30 mg)

Benralizumab is a monoclonal antibody that attracts natural killer cells via antibody-dependent cellular cytotoxicity activity (ADCC activity) to induce direct and rapid depletion of eosinophils in the blood and in the airway. Benralizumab is available as a fixed-dose subcutaneous injection via a prefilled syringe administered once every 4 weeks for the first 3 doses, and then once every 8-weeks thereafter. Benralizumab is also being studied in severe nasal polyposis. The U.S Food and Drug Administration recently granted benralizumab orphan drug designation for hypereosinophilic syndrome (HES) and eosinophilic granulomatosis with polyangiitis (EGPA).

Benralizumab was licensed to AstraZeneca from BioWa, Inc., a wholly-owned subsidiary of Kyowa Hakko Kirin Co., Ltd., and developed by Kyowa Hakko Kirin and AstraZeneca.