

Kyowa Hakko Kirin Enters Agreement with AstraZeneca for Development and Commercialisation of Benralizumab in Asia

Tokyo, Japan, March 24th, 2017—Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, “Kyowa Hakko Kirin”) announces that it has entered an agreement with AstraZeneca (LSE/SSE/NYSE: AZN) for the exclusive rights to benralizumab (generic name) for the treatment of severe asthma and chronic obstructive pulmonary disease (COPD) in Asia.

Benralizumab is an anti-eosinophil monoclonal antibody targeting the IL-5 Receptor that depletes eosinophils through Antibody-Dependent-Cellular-Cytotoxicity. Eosinophils are the biological effector cells that drive inflammation and airway hyper-responsiveness found in approximately 50% of asthma patients, leading to frequent exacerbations, impaired lung function and asthma symptoms.

Under the terms of the agreement, AstraZeneca will pay Kyowa Hakko Kirin \$15 million up-front and subsequent payments for regulatory and commercial milestones, and low double-digit percent sales royalties. AstraZeneca will be responsible for development, and sales and marketing of benralizumab in severe asthma and COPD in 13 Asian countries and regions, except Japan where AstraZeneca already holds the commercialisation rights to benralizumab.

“We are pleased to enter this agreement with our partner AstraZeneca, a global pharmaceutical company with strong commercial bases in Asia.” said Masashi Miyamoto, Executive Officer, Director of Strategic Product Portfolio Department of Kyowa Hakko Kirin. “Through AstraZeneca’s development and commercialisation expertise in respiratory, as well as its strong network across the markets, we will be able to deliver this innovative new drug to patients in Asia.”

In 2015, Kyowa Hakko Kirin entered into an exclusive option agreement with AstraZeneca for the commercialisation of benralizumab in Japan. AstraZeneca exercised the option in 2016 and is responsible for filing an application of manufacturing and marketing approval to the regulatory authority and all sales and marketing activity in Japan.

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 benralizumab

Benralizumab is an investigational anti-eosinophil monoclonal antibody that induces direct, rapid and near-complete depletion of eosinophils, with an onset of action within 24 hours as confirmed in early phase I/II trials. Eosinophils are the biological effector cells that drive inflammation and airway hyper-responsiveness in approximately 50% of asthma patients, leading to frequent exacerbations, impaired lung function and asthma symptoms.

About Asthma

Asthma is a chronic inflammatory disorder of the airways in which the bronchi are reversibly narrowed. It affects people of all ages and is a significant source of morbidity and mortality worldwide. Asthma can be allergic (induced by an immune response to inhaled allergens such as pollen, fungal spores or dust mite particles) or non-allergic (induced by exercise, cough, viral respiratory infection, or inhalation of smoke or chemicals in the workplace). The airway narrowing characteristic of asthma is a response of the immune system to the asthma trigger.

Severe persistent asthma is classified by the frequency of symptoms throughout the day and night, use of reliever inhalers, interference with daily activities, peak flow readings and whether asthma exacerbations require use of inhaled corticosteroids (ICS) more than twice a year. Asthma treatment usually includes ICS that reduce inflammation of the airways to prevent asthma symptoms and exacerbations, combined with long-acting β 2-agonist bronchodilators and a short-acting β 2-agonist or other bronchodilator for relief.

About COPD

COPD is a progressive disease associated mainly with tobacco smoking, air pollution or occupational exposure, which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. Although COPD is widely regarded as a disease of the elderly, 50 percent of patients are estimated to be between 50 and 65 years of age, meaning half of the COPD population is likely to be affected at a stage in their life when they are at the peak of their earning potential and are likely to have major family responsibilities.