

## **Kyowa Hakko Kirin Enters Option Agreement with AstraZeneca for Commercialisation of Benralizumab (KHK4563) in Japan**

Tokyo, Japan, July 16<sup>th</sup>, 2015—Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, “Kyowa Hakko Kirin”) announced that it has entered an agreement with AstraZeneca plc. (London, UK, CEO: Pascal Soriot) for an exclusive option to commercialise benralizumab (generic name / code name: KHK4563) for asthma and chronic obstructive pulmonary disease (COPD) in Japan.

Benralizumab is a monoclonal antibody currently in Phase III development for the treatment of severe uncontrolled asthma and COPD. It targets the IL-5 Receptor and depletes eosinophils which play a key role in inflammatory respiratory disease. Currently, Kyowa Hakko Kirin holds exclusive development and commercialisation rights for benralizumab in Japan and certain countries in Asia, while AstraZeneca has exclusive rights in all other countries including the US and Europe.

The global Phase III results for benralizumab in severe asthma are expected to read out in 2016, with regulatory submissions anticipated later that year in the US and EU. Phase III results and regulatory filing in COPD are expected in 2018 in the US and EU.

Under the terms of the agreement, AstraZeneca will pay Kyowa Hakko Kirin a \$45 million up-front option fee and subsequent payments for regulatory filing, approval and commercial milestones, and sales royalties. Kyowa Hakko Kirin will continue to be responsible for the research and development of benralizumab in Japan. On exercising the option, AstraZeneca will be responsible for all sales and marketing in asthma and COPD in Japan. Kyowa Hakko Kirin will retain the rights to participate in certain commercial activities alongside AstraZeneca.

Masashi Miyamoto, Ph.D., Executive Officer, Director, Strategic Product Portfolio Department of Kyowa Hakko Kirin said: “ We are delighted to enter this agreement with our long-standing strategic partner AstraZeneca. Through this new agreement, we will be able to maximise the medical benefits that this innovative new drug could bring to patients in Japan.”

Marc Dunoyer, Chief Financial Officer, AstraZeneca, said: “Japan is the second largest pharmaceutical market in the world and one of our growth platforms. The agreement with Kyowa Hakko Kirin increases our focus on respiratory diseases, a main therapy area for AstraZeneca, and provides the opportunity to bring an innovative potential medicine to patients in Japan who are waiting for new treatment options.”

Benralizumab is out-licensed from BioWa, Inc., a wholly-owned subsidiary of Kyowa Hakko Kirin, to AstraZeneca. Under the terms of the original license agreement, Kyowa Hakko Kirin/BioWa had exclusive development and commercialisation rights for benralizumab in

Japan and certain countries in Asia. AstraZeneca has exclusive rights for benralizumab in all other countries including the US and Europe. BioWa is eligible for milestone payments and royalties related to the development and commercialisation of benralizumab in those countries.

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 (KHK4563)**

Benralizumab is an investigational humanised monoclonal antibody directed at the alpha sub-unit of the interleukin-5 receptor (IL-5R $\alpha$ ) that depletes eosinophils, a key target cell in inflammatory respiratory disease.

### **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  $\beta$ 2-agonist bronchodilators and a short-acting  $\beta$ 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.

**About Kyowa Hakko Kirin**

Kyowa Hakko Kirin is a research-based life sciences company with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology and immunology/allergy, Kyowa Hakko Kirin leverages leading-edge biotechnologies centered on antibody technologies, to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, we are working to realise our vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and comfort of people around the world. More information can be found at <http://www.kyowa-kirin.com>

**About AstraZeneca**

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: [www.astrazeneca.com](http://www.astrazeneca.com).