

Top-Line Results from the Benralizumab Phase III Programme in Severe Asthma

Tokyo, Japan, May 17th, 2016 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") announced today that AstraZeneca (BK, London, CEO: Pascal Soriot) obtained the positive top-line results that benralizumab, a potential new medicine and anti-eosinophil monoclonal antibody, was well tolerated and achieved the primary end-point in two pivotal Phase III registrational trials (SIROCCO and CALIMA), demonstrating significant reductions in the annualized asthma exacerbation rate compared to placebo.

The trials evaluated the efficacy and safety of two dose regimens of benralizumab as an add-on therapy for severe, uncontrolled asthma with eosinophilic inflammation.

In SIROCCO and CALIMA, the primary analysis population included patients on high-dose inhaled corticosteroids (ICS) plus long-acting β 2-agonist (LABA) with a baseline blood eosinophil count \geq 300 cells/microliter. The safety and tolerability findings for benralizumab were generally consistent with those reported in previous studies. Patients were randomized to receive benralizumab 30 mg every 4 weeks; 30 mg every 4 weeks for the first three doses followed by 30 mg every 8 weeks; or placebo.

"We are delighted with the positive results from these pivotal Phase III studies of benralizumab in patients with uncontrolled asthma. Benralizumab is Kyowa Hakko Kirin's second product using the POTELLIGENT[®] technology that enhances the activity of antibody-dependent cell-mediated cytotoxicity (ADCC). We believe benralizumab has the potential to deliver a new therapeutic option for uncontrolled asthma patients with eosinophilic phenotype." said Yoichi Sato, Managing Executive Officer, Vice President, Head of Research and Development Division of Kyowa Hakko Kirin.

Eosinophils are the biological effector cells which drive inflammation and airways hyper-responsiveness in approximately 50% of asthma patients, leading to frequent exacerbations, impaired lung function and reduced quality of life. Benralizumab is an anti-eosinophil monoclonal antibody that depletes eosinophils via ADCC, the process by which natural killer cells are activated to target eosinophils. Benralizumab induces direct, rapid, and near complete depletion of eosinophils in the bone marrow, blood and target tissue.

Results from the SIROCCO and CALIMA trials will be presented at a future medical meeting.

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 Asthma

Asthma is a common, chronic condition in which inflammation and narrowing of the airways may cause wheezing, breathlessness, chest tightness and coughing. Asthma currently affects the health and day-to-day lifestyles of 315 million individuals worldwide, and by 2020 will likely increase in numbers to as many as 400 million people.

About SIROCCO and CALIMA

SIROCCO and CALIMA are both part of the comprehensive WINDWARD programme in asthma, the largest Phase III development programme for a biologic in respiratory disease. (A total of 2,511 patients: 1,205 in SIROCCO and 1,306 in CALIMA)

About Benralizumab

Benralizumab is an anti-eosinophil monoclonal antibody that binds to the human interleukin-5 receptor alpha subunit (IL-5R α) expressed on the surface of eosinophils and basophils. In binding to the receptor, benralizumab leads to active, rapid and direct eosinophil depletion (apoptosis by ADCC) through natural killer cells.

Kyowa Hakko Kirin/BioWa have granted to AstraZeneca exclusive development and commercialisation rights for benralizumab in certain countries including the US and Europe and an exclusive option to commercialise benralizumab in Japan and are eligible for milestone payments and royalties related to the development and commercialisation of benralizumab in those countries. Kyowa Hakko Kirin/BioWa have all rights for benralizumab in certain countries in Asia. Kyowa Hakko Kirin retains the rights to participate in certain commercial activities alongside AstraZeneca in Japan when the option is exercised by AstraZeneca.