

Kyowa Hakko Kirin Entered into an Agreement with Medgenics for the Clinical Development of anti-LIGHT Monoclonal Antibody

Tokyo, Japan, June 6th, 2016 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo 4151; President and CEO: Nobuo Hanai, “Kyowa Hakko Kirin”) announced that it entered into an agreement with Medgenics, Inc. (NYSE: MDGN, “Medgenics”) for the clinical development of Kyowa Hakko Kirin’s first-in-class anti-LIGHT monoclonal antibody for Severe Pediatric Onset Inflammatory Bowel Disease (IBD).

This anti-LIGHT monoclonal antibody is a Phase 2-ready first in class human monoclonal antibody offering a novel molecular approach to treating IBD and potentially other autoimmune diseases. The antibody binds the pro-inflammatory cytokine, LIGHT (ligand for herpesvirus entry mediator), which is believed to be a major contributor to the chronic relapsing inflammation of IBD and other autoimmune diseases.

Under the terms of this agreement, Medgenics plans to initiate a signal finding study testing the drug in Severe Pediatric Onset IBD. Medgenics has an option to license rights to the development program. Upon exercising the option following completion of the signal finding study, Medgenics will make a one-time upfront payment to Kyowa Hakko Kirin in the low single-digit millions (USD). Kyowa Hakko Kirin will then select one of two potential collaboration structures: a co-development/co-commercialization partnership or a licensing arrangement. Medgenics will have commercialization rights in the United States and Canada in both structures, and will also add commercialization rights in Europe if Kyowa Hakko Kirin selects the licensing arrangement. Kyowa Hakko Kirin will have commercialization rights in the rest of the world under both structures, as well as Europe in the co-development/co-commercialization structure. Terms for both structures have been pre-agreed and include a combination of royalties and profit-sharing.

“We are excited to enter an agreement with Medgenics in this new era of genomic medicine,” said Yoichi Sato, Director of the Board, Managing Executive Officer, Vice president, Head of Research and Development Division of Kyowa Hakko Kirin. “We believe in the potential of the anti-LIGHT antibody and we are looking forward to initiating development activities with our new partner in order to provide better treatment options for pediatric IBD patients.”

We are pleased to establish this collaboration with a premier biologics partner in Kyowa Hakko Kirin,” said Mike Cola, Chief Executive Officer of Medgenics. “This novel opportunity is a further example of the capability of the Medgenics’ genomic medicine platform to accelerate impactful therapies into the clinic.”

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 Severe Pediatric Onset Inflammatory Bowel Disease (IBD)

Inflammatory Bowel Disease (IBD) is a disease that causes chronic relapsing inflammation of the intestines. There are two major types of IBD; Ulcerative Colitis which affects the colon, and Crohn's Disease which effects the entire GI tract. Both diseases are treated with a variety of anti-inflammatory drugs, including steroids, antibiotics, and biologics. Disease etiology is not well understood, but it is believed that both genetics and environmental factors play a major role at various stages and ages of disease onset. IBD affects people of all ages with approximately 2.0 million people affected by the disease in the United States and Europe. The pediatric form of the disease is less common but frequently more severe, affecting more than 50,000 children in the USA. The incidence appears to be increasing. The disease in children is often more aggressive than in adults, more frequently leading to complications, hospitalization, surgery and even death. In children, IBD can also impact physical and emotional growth, interfere with school and social development.

About Medgenics

Medgenics is dedicated to unlocking the potential of genomic medicine to identify and treat patients with life-altering conditions. Its efforts, including its internal research and development and ongoing sponsored research and licensing agreements with a well-respected pediatric academic medical center, give Medgenics the ability to focus on the underlying genetic pathway of pediatric diseases with the goal of finding therapeutic solutions for subpopulations of both children and adults living with rare and other difficult-to-treat diseases. Medgenics is also the developer of TARGTMM (Transduced Autologous Restorative Gene Therapy), a proprietary gene therapy platform. For more information, visit the Company's website at www.medgenics.com.