Kyowa Kirin Enters into License Agreement with Cerecor Inc. Affiliate Aevi Genomic Medicine for All the Anti-LIGHT Antibody Indications Worldwide

Tokyo, Japan, March 29, 2021--Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announced that the company has expanded its collaboration with Cerecor Inc.'s affiliate, Aevi Genomic Medicine, LLC (Rockville, MD and Chesterbrook, PA, USA, "Cerecor") by granting Cerecor exclusive worldwide rights to develop, manufacture and commercialize Kyowa Kirin and La Jolla Institute created potential first-in-class fully human anti-LIGHT (Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for HVEM, a receptor expressed by T lymphocytes) monoclonal antibody, CERC-002.

Kyowa Kirin initially entered into the original clinical development and option agreement with Cerecor in June 2016 for clinical development and commercialization of the antibody for Severe Pediatric Onset Inflammatory Bowel Disease (IBD) and certain other rare and orphan pediatric indication with options in North America and Europe, and subsequently Kyowa Kirin granted additional option rights to Cerecor for worldwide development, manufacturing and marketing rights for COVID-19 ARDS in May 2020. Under the terms of this new agreement, Kyowa Kirin will license to Aevi exclusive global rights to CERC-002 for all indications, while Kyowa Kirin has an option to retain the rights in Japan.

Kyowa Kirin will receive an up-front payment from Cerecor, and is eligible to receive additional payments depending on development and commercial milestones, as well as sales-based royalties.

"I am pleased to expand our collaboration with Cerecor through the execution of this agreement. Cerecor has strived to develop the antibody not only for the original indication, Severe Pediatric IBD, but has also advanced development of CERC-002 in patients suffering from COVID-19 ARDS in a very short period of time," said Tomohiro Sudo, Executive Officer, Director of Strategy Product Planning Department of Kyowa Kirin. "I strongly believe that Cerecor will continue to expedite their activities to expand the use of this antibody in order to contribute to the wellbeing of patients and their families."

The Kyowa 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 CERC-002 (anti-LIGHT monoclonal antibody)

CERC-002 is a fully human anti-LIGHT or tumor necrosis factor superfamily member 14 (TNFSF14) monoclonal antibody licensed from Kyowa Kirin Co., Ltd. It is the only clinical stage anti-LIGHT therapy and has the potential to treat a number of LIGHT-associated immune diseases including cytokine storm-induced COVID-19 ARDS. It is currently in development for pediatric onset Crohn's disease and cytokine storm induced COVID-19 ARDS. Cerecor Inc. has also developed a validated, high sensitivity serum/plasma free LIGHT assay in collaboration with Myriad RBM.

Role of LIGHT in Acute Inflammatory Response

LIGHT (homologous to Lymphotoxin, exhibits inducible expression and competes with HSV glycoprotein D for binding to herpesvirus entry mediator, a receptor expressed on T lymphocytes) is a cytokine with inflammatory actions encoded by the Tumor Necrosis Factor Super Family 14 gene. LIGHT has been shown to play a key role in the immune response to viral pneumonia. LIGHT plays an important role in regulating immune responses in the lung and gut. It stimulates T Cell and B Cell response as well as induces the release of other cytokines such as IL-1, IL-6, IL-8, IL-10, TNFs and GM-CSF[1~3].

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. 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 COVID-19 ARDS[4]

COVID-19 usually begins as an upper respiratory tract infection; however, for some patients, the SARS-CoV-2 virus enters the lower respiratory tract and causes direct injury to the lungs by filling the alveoli (air sacs) with excess fluid. As decrease in oxygenation occurs in the blood, breathing becomes distressed and organs become oxygen-deficient. The lungs attempt to heal, but the resulting inflammatory response / cytokine storm often ends up damaging the lungs further.

This severe inflammatory disease of the lungs is called acute respiratory distress syndrome (ARDS). ARDS is a condition most commonly associated with illnesses such as sepsis and bacterial

pneumonia—and now with COVID-19. When a patient presents with symptoms associated with ARDS—shortness of breath, chest pain, rapid heart rate and reduced blood oxygen levels—they are transported to the intensive care unit (ICU) to be monitored and possibly treated with artificial or mechanical ventilation.

About Cerecor Inc.

Cerecor Inc. is a biopharmaceutical company focused on becoming a leader in the development and commercialization of treatments for rare and orphan diseases, and Aevi Genomics Medicine, LLC is a wholly-owned subsidiary of Cerecor Inc. The company is advancing its clinical-stage pipeline of innovative therapies that address unmet patient needs within rare and orphan diseases. The company's rare disease pipeline includes CERC-801, CERC-802 and CERC-803, which are in development for congenital disorders of glycosylation and CERC-006, an oral mTORc1/c2 inhibitor in development for the treatment of complex lymphatic malformations. The company is also developing two monoclonal antibodies, CERC-002, and CERC-007. CERC-002 targets the cytokine LIGHT (TNFSF14) and is in clinical development for treatment of severe pediatric-onset Crohn's disease, and COVID-19 acute respiratory distress syndrome. CERC-007 targets the cytokine IL-18 and is in clinical development for the treatment of Still's disease (adult onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (sJIA)), and multiple myeloma (MM). CERC-006, 801, 802 and 803 have all received Orphan Drug Designation and Rare Pediatric Disease Designation, which makes all four eligible for a priority review voucher upon FDA approval.

For more information about Cerecor, please visit www.cerecor.com.

Reference:

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