Better Health, Brighter Future

News Release

Topline Results from NIH-Sponsored Clinical Trial of Investigational COVID-19 Hyperimmune Globulin Medicine

Osaka, JAPAN, April 2, 2021 – Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) ("Takeda") today announced that the CoVIg-19 Plasma Alliance announced the phase 3 clinical trial to evaluate potential COVID-19 hyperimmune medicine did not meet its endpoints. No serious safety signals were raised in the trial. Takeda is one of the founding companies of the Alliance. Please see the attached press release for details.

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CoVIg-19 PLASMA ALLIANCE

Working Together to Fight COVID-19 with Immunoglobulin (Ig) Therapy

CoVIg-19 Plasma Alliance Announces Topline Results from NIH-Sponsored Clinical Trial of Investigational COVID-19 Hyperimmune Globulin Medicine

- *Phase 3 Inpatient Treatment With Anti-Coronavirus Immunoglobulin (ITAC) Clinical Trial Sponsored and Funded by the National Institute of Allergy and Infectious Diseases (NIAID), Part of the National Institutes of Health (NIH), Did Not Meet Its Endpoints to Show Efficacy in Adults Hospitalized With COVID-19*

OSAKA, Japan and KING OF PRUSSIA, Pa., USA – April 2, 2021 – The CoVIg-19 Plasma Alliance today announced that the Phase 3 Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) clinical trial sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), did not meet its endpoints. No serious safety signals were raised in the trial.

The study aimed to determine whether an investigational anti-coronavirus hyperimmune intravenous immunoglobulin (H-Ig) medicine (referred to by the Alliance as CoVIg-19) could reduce the risk of disease progression when added to standard of care treatment including remdesivir in hospitalized adult patients at risk for serious complications. Analyses remain ongoing and NIAID and the INSIGHT Network intend to publish the full results of the trial soon.

“While the results of this particular clinical trial are disappointing, we are proud that as an industry we proactively and collaboratively pursued this work, and that the program may contribute to a growing understanding of this challenging virus and strategies for patient care. Since we embarked on this development program, and throughout the pandemic, we have learned much from our scientific research. Importantly, we learned that as an industry we have the fortitude and capability to quickly work together for the greater good of human health,” said Bill Mezzanotte, MD, MPH, Executive Vice President, Head of Research and Development and Chief Medical Officer, CSL Behring and co-leader of the CoVIg-19 Alliance.

“We are especially proud that we pooled resources, brought our plasma expertise and infrastructure together at our own cost to benefit public health and added to our understanding of a complex field. We are extremely thankful to all those who collaborated day and night for one year in testing circumstances to develop and manufacture a potential solution for COVID-19, including those organizations from outside the industry who chose to support us,” said Julie Kim, president of Plasma-Derived Therapies Business Unit, Takeda and co-leader of the CoVIg-19 Alliance. “We express our sincere gratitude to the COVID-19 survivors who generously donated their plasma to make our work possible, the patients who graciously participated in the trial, and to the regulatory and government agencies for their partnership and flexibility to support our efforts.”

Following the outcome of the ITAC trial, the CoVIg-19 Plasma Alliance’s work now concludes. The one-year collaboration involving organizations from across the world has strengthened relationships within and outside the industry, enabled a renewed perspective toward pragmatic regulation based on scientific evidence and need, and provided a well-defined, legally compliant framework for future collaborative opportunities to address urgent public health needs

About the ITAC Trial

The Phase 3 Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) clinical trial is a global, multi-center, double-blind, placebo-controlled, randomized trial sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). It was designed to test the safety, tolerability and efficacy of a combination treatment regimen for coronavirus disease 2019 (COVID-19) consisting of the antiviral remdesivir along with an anti-coronavirus hyperimmune intravenous immunoglobulin (H-Ig), which contains a highly concentrated solution of antibodies that neutralize SARS-CoV-2. The antibodies in the H-Ig come from the liquid portion of blood, or plasma, donated by healthy people who have recovered from COVID-19.

Through the NIAID-funded INSIGHT Network, the study team enrolled nearly 600 adult patients at 63 sites in the United States and 10 other countries on five continents. Volunteers were eligible for the trial if they had been hospitalized for COVID-19 and had symptoms for 12 days or fewer without life-threatening organ dysfunction or end-organ failure. Four companies provided investigational H-Ig materials for the trial, including CSL Behring and Takeda on behalf of the CoVIg-19 Plasma Alliance, as well as Emergent BioSolutions and Grifols. Further information about the ITAC trial is available at ClinicalTrials.gov under study identifier NCT04546581.

About the CoVIg-19 Plasma Alliance

In an effort to help fight against the COVID-19 pandemic, the CoVIg-19 Plasma Alliance was formed in April 2020 to help develop a potential plasma-derived therapy for people at risk for serious complications from COVID-19. The Alliance brought together world-leading plasma companies to work on the development of an investigational unbranded polyclonal anti-SARS-CoV-2 hyperimmune globulin medicine intended for the treatment of patients at risk for serious complications from COVID-19. The hyperimmune globulin, known as CoVIg-19, is a high-quality pharmaceutical product that contains purified, consistent and concentrated levels of convalescent antibodies.

Co-founded by CSL Behring and Takeda, the Alliance also included BioPharma Plasma, Biotest, GC Pharma, LFB, National Bioproducts Institute, Octapharma and Sanquin. The Bill & Melinda Gates Foundation provided advisory support. Microsoft provided technology including the Alliance website and the Plasma Bot for donor recruitment. Organizations including Pall and Uber Health also made in-kind contributions to the Alliance.

The Alliance is also part of “The Fight Is In Us” campaign, a coalition seeking to mobilize tens of thousands of people in the United States who have recovered from COVID-19 to donate their blood plasma. Individuals who have recovered from COVID-19, or know someone who has, can visit TheFightIsInUs.org to understand if they may be eligible to donate and find a nearby blood or plasma donor center using a simple self-screening tool.

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CoVIg-19 PLASMA ALLIANCE

Working Together to Fight COVID-19 with Immunoglobulin (Ig) Therapy

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