

First Patient Enrolled in NIH Phase 3 Trial to Evaluate Potential COVID-19 Hyperimmune Medicine

- *The Alliance’s anti-COVID-19 Hyperimmune Globulin (CoVIg-19) medicine is under evaluation as part of the trial and may become one of the earliest treatments for hospitalized individuals at risk for serious complications of COVID-19*
- *The CoVIg-19 Plasma Alliance urges anyone who has recovered from COVID-19 to consider donating plasma. To learn more, please visit [TheFightIsInUs.org](https://www.thefightisInUs.org).*

Osaka, JAPAN and King of Prussia, Pa., USA – October 8, 2020 – The CoVIg-19 Plasma Alliance, an unprecedented collaboration of leading plasma companies supported by global organizations outside the plasma industry, today confirmed that patients are now being enrolled in the Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) Phase 3 clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The trial will evaluate the safety, tolerability and efficacy of an investigational anti-coronavirus hyperimmune intravenous immunoglobulin (H-Ig) medicine for treating hospitalized adults at risk for serious complications of COVID-19 disease. If successful, the Alliance’s H-Ig may become one of the earliest treatment options for hospitalized COVID-19 patients.

This global multi-center, double-blind, placebo-controlled, randomized trial will enroll 500 adult patients at up to 58 sites in the United States, Mexico and 16 other countries on five continents (utilizing the NIH’s global INSIGHT Network), who have been hospitalized for COVID-19 and have had symptoms for 12 days or fewer without life-threatening organ dysfunction or end-organ failure. Patients will receive remdesivir as standard of care, allowing the safety and efficacy of H-Ig to be evaluated when given along with remdesivir treatment. The investigational H-Ig materials for the trial will be provided by CSL Behring and Takeda on behalf of the CoVIg-19 Plasma Alliance, as well as by two other companies.

“The rapid progress we’ve made since we initiated this program just a few months ago to reach this key milestone of enrolling patients in the trial is a powerful testament to the collaboration, determination and innovation taking place across the biomedical community as we work to fight the COVID-19 pandemic,” said Julie Kim, President of Plasma-Derived Therapies Business



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

Unit, Takeda and co-leader of the CoVIg-19 Alliance. “This study will help us understand how CoVIg-19 could potentially become an important therapeutic option. To support our efforts, we encourage all those people who have recovered from COVID-19 to donate their plasma, which contains vital antibodies that have fought off the disease and could help others do the same.”

“When we created the CoVIg-19 Plasma Alliance in April, the goal was to partner to accelerate our timelines so that we could develop and deliver a reliable and sustainable treatment option for people suffering the impact of COVID-19 and to support countries around the world in their efforts to fight the current pandemic,” 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. “Thanks to the unprecedented collaboration from the CoVIg-19 Plasma Alliance members, commitment from those who have recovered from the virus and generously chosen to donate their plasma, as well as the strong support from the NIH, we are hopeful that data from the clinical trial will be available before the end of the year. If the trial proves successful, this therapy could bring new hope to those suffering serious health consequences from COVID-19.”

Further information about the ITAC trial is available at ClinicalTrials.gov under study identifier [NCT04546581](https://ClinicalTrials.gov/ct2/show/study/NCT04546581).

How you can help: Donate plasma

A coalition of world-leading medical and research institutions, blood centers, life science companies, technology companies, philanthropic organizations, and COVID-19 survivor groups has come together to support the rapid development of potential new therapies for patients with COVID-19. Working together under the “The Fight Is In Us” campaign, the coalition is seeking to mobilize tens of thousands of people in the United States who have recovered from COVID-19 to donate their blood plasma. Donating blood plasma is a generally safe and proven process. 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. The coalition offers more than 1,500 locations at which COVID-19 survivors can choose to donate.

About the CoVIg-19 Plasma Alliance

In an effort to help fight against the COVID-19 pandemic, the Alliance was created in April 2020



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to help develop a potential plasma-derived therapy for people at risk for serious complications from COVID-19. The CoVIg-19 Plasma Alliance brings together world-leading plasma companies to work on the development of an investigational unbranded polyclonal anti-SARS-CoV-2 hyperimmune globulin medicine with the potential to treat patients who are at risk for serious complications from COVID-19. The hyperimmune globulin is a high quality pharmaceutical product that contains purified, consistent, and concentrated levels of convalescent antibodies.

The “I” and “g” in CoVIg-19 stand for immune globulin, which the CoVIg-19 Plasma Alliance will use to concentrate the antibodies into a potential medicine. The Alliance, formed by CSL Behring and Takeda, also includes the leading-edge expertise of founding members Biotest, BPL, LFB, and Octapharma, along with additional industry members ADMA Biologics, BioPharma Plasma, GC Pharma, Liminal BioSciences, National Bioproducts Institute and Sanquin. The Bill & Melinda Gates Foundation is providing advisory support. Microsoft is providing technology including the Alliance website and the Plasma Bot for donor recruitment. Organizations including Pall and Uber Health are also making contributions to the CoVIg-19 Plasma Alliance. Experts from the Alliance are collaborating across key aspects such as plasma collection, clinical trial development, and product manufacturing.

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