CoVIg-19 PLASMA ALLIANCE

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

March 4th, 2021

To the Ministers of Health in the Member States of the European Union and Switzerland

Regarding: Availability and allocation of investigational plasma-derived therapy against COVID-19

Dear Minister,

I am writing to you on behalf of the CoVIg-19 Plasma Alliance.

The purpose of this communication is to provide you with an update on our program to develop a **plasma-derived human SARS-CoV-2 Hyperimmune globulin (H-Ig) therapy** as a potential treatment for patients hospitalized with COVID-19, and to be advised of your interest in receiving a quantity of this therapy should it receive authorization in the EU, and as supplies may allow.

As we continue to learn how COVID-19 manifests, a variety of preventative and therapeutic approaches will be needed to treat individuals at different stages of disease. The SARS-CoV-2 investigational H-Ig medicine has been developed with the **potential to treat individuals who have been hospitalized with the infection** but are still in the early stages of the disease.

To expedite development, the **CoVIg-19 Plasma Alliance**, founded by CSL Behring and Takeda in April 2020, and including Biopharma, Biotest, GC Pharma, LFB, NBI, Octapharma and Sanquin, **collaborated with the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health (NIH) on an innovative multi-national Phase 3 pivotal clinical trial.** The ITAC clinical study is expected to complete by mid-March, having enrolled more than 500 patients globally. If data (expected in early April 2021) are positive, several Alliance member companies will pursue regulatory submissions to be able to make this therapeutic option available to patients as quickly as possible.

In the interest of public and patient health, **Alliance member companies have collaborated to develop and produce the H-Ig at their own expense and have committed to donate product produced on behalf of the Alliance**, if regulatory authorization is granted. They also have the option to continue to manufacture and share the information to do so with other plasma fractionators around the world if patient need remains high.

As with all plasma-derived therapies, how much H-Ig the Alliance can produce depends on the convalescent plasma donations actually received. Given this reliance on donations, to date we have been able to produce quantities of product in the range of thousands of doses versus the typically much larger scale you might expect for vaccines and products created with recombinant or synthetic materials. At this time, we anticipate up to **several thousand doses in total can be made available across the EU region once authorized.** Additional supply for future distribution is under preparation and dependent on regulatory outcomes and dynamics of the disease and vaccination efforts around the world.

The Alliance has developed prospectively a **shared algorithm to ensure equitable allocation of available product and to best meet greatest patient need**. This dynamic model prioritizes countries where regulatory authorization is expected based on real time data (sourced from the WHO database) indicating the **severity** (number of deaths daily) and **progression** (change in weekly cases) of the pandemic. It also provides incremental allowance for those countries that have contributed convalescent plasma. The Alliance will run the allocation model and confirm potential volume for your particular country around the time we plan to submit for EU authorization.

If you would like your country to be considered to receive human SARS-CoV-2 immunoglobulin therapy as a donation (assuming and following EU authorization), **I kindly request that you indicate this by 15th March via email to** 5.1.2e @takeda.com**].** I will then send you a document to confirm your interest in receiving a donation with associated terms and conditions. Importantly, we will require you to specify a location and named recipient with whom to organize delivery of a potential donation as early as possible. **Please be advised, that only those countries that respond expressing interest in receiving the SARS-Cov-2 immunoglobulin therapy will be included in the allocation calculation that will determine product distribution upon authorization.**

If you would like to discuss further, I will be glad to refer you to a team within our company who can answer your questions and provide further details on behalf of the Alliance.

Yours sincerely,

5.1.2e

5.1.2e