Aegros Releases Top-Line Interim Clinical Trial Results of its COVID-19 Hyperimmune

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Aegros, an Australian clinical-stage biopharmaceutical company leader in the development and manufacture of plasma derived medicinal products (PDMPs), today announced positive top-line interim results from its CHAT clinical trial.

Top-line interim results indicate that Aegros' COVID-19 hyperimmune provides higher levels of antibodies compared to high-titer convalescent plasma. These results are in line with Aegros' pre-clinical expectations.

CHAT compared Aegros' COVID-19 hyperimmune to COVID-19 convalescent plasma. The hyperimmune was manufactured using Aegros' patented Haema*frac*® process. A hyperimmune is an intravenous immunoglobulin rich in antibodies that can provide passive immunity for immunocompromised individuals.

The key findings of CHAT include:

1. The mean maximum antibody levels (Cmax), measured using the Abbott AdviseDx SARS-CoV-2 antibody assay system for the convalescent plasma (n=11) and immunoglobulin (n=11) arms was 154.7 (± 43.0) AU/mL and 685 (± 224.1) AU/mL respectively – a fourfold increase over convalescent plasma.

2. The safety profiles of both convalescent plasma and immunoglobulin were as expected.

These trial results are incredibly important for many Australians unable to benefit from the current COVID-19 vaccines because of with underlying conditions such as immunodeficiency, certain cancers, and rare diseases..

"These results mark a significant milestone in our ongoing commitment to advancing healthcare and addressing the unmet needs of immunocompromised individuals whose responses to vaccination are less than optimal," said Mr John Manusu, Aegros Cofounder and Managing Director.

"By announcing these results today, Aegros signals that it is an Australian manufacturer of plasma medicines that has achieved what many have failed to do; make and test a hyperimmune against SARS-CoV-2 to address a critical need amongst those who cannot benefit from a vaccine,"

"This result shows that Haema*frac*®, our cutting-edge process of fractionation, not only meets the specifications required for an immunoglobulin product but can successfully provide a higher level of passive immunity against COVID-19 disease than convalescent plasma," said Professor Hari Nair, Cofounder and Executive Chair Aegros.

About the CHAT Clinical Trial:

- The CHAT study was designed to compare SARS-CoV-2 antibodies given as convalescent plasma with Aegros' hyperimmune immunoglobulin, as well as the safety of the immunoglobulin preparation.
- Healthy clinical trial volunteers were infused with a single 32ml dose of 5% hIVIG[1] preparation.

Next Steps:

With these positive top-line results, Aegros is committed to advancing the development of its COVID-19 hyperimmune.

These results will be analysed and prepared for submission to the Australian Therapeutics Goods Administration (TGA), who will assess this product for registration. Aegros will work closely with regulatory authorities to determine the appropriate next steps in the development and potential registration of this promising therapy.

Subject to their approval, Aegros will then be issued with a listing on Australian Register of Therapeutic Goods (ARTG) for this COVID-19 hyperimmune, after which Aegros can bring this product to market.

About Aegros

Aegros is an Australian technology leader in the US$28B global therapeutic plasma market. Its GMP licensed Haema*f*rac® lifts process yields to over 85%, reducing cost and carbon emissions. The Company expects to lodge applications for its first product, a Covid-19 hyperimmune, shortly.

Aegros is designing and constructing a 1 million litre Haema*f*rac® facility with support from the Queensland Government's Invested In Queensland program which is expected to come online in 2026. This Haema*f*rac® facility will produce Albumin, IVIG and other plasma products for the Australian and overseas markets.

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[1] hIVIG – Hyperimmune Intravenous Ig.