BioAegis Therapeutics and EastHORN Expand Phase 2 COVID-19 Clinical Trial within Spain and into Romania

Dundee, Nov 18, 2020 (Issuewire.com) - BioAegis' Phase 2 clinical trial of recombinant human plasma gelsolin (rhu-pGSN) for the treatment of severe COVID-19 was initiated by EastHORN in August in Spain. Approval has also been received from the Romanian National Agency for Medicines and Medical Devices (NMMD) to extend the trial into Romania. The first Romanian patients were recruited this week.

Iain Gordon, Chief Business Officer at EastHORN commented, *"Since spring this year, we have been working with regulatory agencies and sites in western Europe to bring potential COVID treatments to the region. The first COVID patients in the BioAegis trial were treated in Spain in August and we are delighted to say that patients in Romania have now also started treatment. BioAegis' product is one of the first novel COVID treatments to be trialled in Romania and we are privileged to be able to help BioAegis lead the way in this country. There are far fewer options for patients here and it is more important than ever that patients get access to medical research in all countries across Europe - and beyond. In addition to acknowledging the hard work of the team in our Bucharest office, we also have to pay tribute to the enthusiasm of the medical staff and the responsiveness of the regulatory authorities."*

The study has now recruited 50% of the expected enrollment and the independent Data Safety Monitoring Board (DSMB) has recently recommended continuation of recruitment based on a review of the safety data. The study assesses rhu-pGSN and its ability to regulate the overactive inflammatory response, often responsible for causing lung damage and death in COVID-19 patients. Rhu-pGSN does not compromise the immune response unlike other immunosuppressive anti-inflammatory agents (e.g. dexamethasone). Low levels of this human plasma protein are associated with severe illness, organ failure and mortality in COVID-19 patients.

According to Susan Levinson, PhD, CEO of BioAegis, "*The independent Data Safety Monitoring Board has reviewed data from the initial patients and recommends that we continue the study as planned. With enrollment numbers growing, we look forward to receiving further data including clinically meaningful endpoints in these severely ill COVID-19 patients, once the study is completed."*

Gelsolin is a Key Component of the Body's Immune System
Gelsolin is a human protein that is abundant in healthy individuals. It is a *'master regulator of inflammation'.* In the case of severe injury or infection, the body's supply of gelsolin becomes depleted, which can lead to an overexuberant inflammatory response, organ damage and death, as seen in COVID-19. With the ability to replete gelsolin depleted by disease with rhu-pGSN, BioAegis is in a unique position to deliver therapeutics that have the potential to disrupt the course of the cytokine storm created by COVID-19.

Supplementing depleted systemic levels of gelsolin has enormous potential to prevent debilitating and potentially lethal ravages of inflammation, without compromising its essential function to fight infection and promote repair. Its unique qualities are:

- **Host-based, not pathogen specific.** Recent findings demonstrate gelsolin's ability to treat both viral and bacterial infections, even those resistant to antibiotics.
- **Naturally occurring human protein.** Gelsolin is part of our innate immune system and our

body’s first line of defense against pathogens.
- **Controls excess inflammation without suppressing the immune response to threats.**Unlike current anti-inflammatory treatments and steroids rhu-pGSN is non-immunosuppressive.

About EastHORN

EastHORN Clinical Services, is a full-service clinical contract research organisation with operations, staff and offices across Europe, stretching from Spain to Russia.

About BioAegis
BioAegis Therapeutics Inc. is a New Jersey based clinical stage, private company whose mission is to capitalize on a key component of the body’s innate immune system, gelsolin, to prevent adverse outcomes in diseases driven by inflammation and infection.

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