BioAegis Therapeutics Completes Enrollment in its Phase 1b/2a **Dose-Ranging Safety Study** of Recombinant Plasma Gelsolin for Community-Acquired Pneumonia

MORRISTOWN, NJ (March 18, 2019). BioAegis Therapeutics Inc. announced that it has completed patient enrollment in its Phase 1b/2a study of recombinant plasma gelsolin (rhu-pGSN) as adjunctive therapy for patients requiring hospitalization because of Community-Acquired Pneumonia (CAP).

A Novel Approach to Create a New Treatment Paradigm

Severe CAP is the lead indication of this clinical-stage company that addresses infectious, inflammatory and degenerative diseases with supplementation of an endogenous protein that is depressed in these disorders. Patients were treated with recombinant human plasma gelsolin (rhu-pGSN) or a matching placebo in this blinded randomized clinical trial.

The Data Safety Monitoring Board (DSMB) met on 4 March 2019 to review the safety profile for the 12 mg/kg multiple-dose regimen (cohort 3). **The review did not identify any safety concerns.** Accordingly, the DSMB recommended enrollment into the last cohort at a 24 mg/kg multiple-dose level (cohort 4), and this enrollment was rapidly completed ahead of schedule. The study will conclude in early April, with first results expected this summer.

Severe Community Acquired Pneumonia

Severe CAP is a leading cause of morbidity and death around the world. According to the **American Thoracic Society**, pneumonia mortality in the USA has remained essentially unchanged since antibiotics first became widely available more than a half a century ago. Significant numbers of CAP patients develop short-term and long-term complications, placing a significant burden on the healthcare system. Survivors often require ongoing care for lingering cardiopulmonary, neurocognitive, and other functional disabilities even after hospital discharge.

Low pGSN Levels at the time of Admission Strongly Correlate with Later Poor Clinical Outcomes

BioAegis, together with investigators at **Vanderbilt** and **Northwestern Universities** along with CDC scientists, had previously demonstrated that hospitalized patients with CAP have depressed levels of plasma gelsolin at presentation. The magnitude of this depression predicts the risk of subsequent adverse clinical events.

Consistent Experimental Results in Gram-Negative and Gram-Positive Infections, even with Antibiotic-Resistant Pathogens

The therapeutic efficacy of rhu-pGSN supplementation has been consistently demonstrated in greater than 25 infectious and non-infectious animal models of common diseases. **Moreover, due to its host-based mechanisms of action, rhu-pGSN has been efficacious against antibiotic-resistant gram-positive and gram-negative pathogens.**

Susan Levinson, PhD, Chief Executive Officer of BioAegis stated, “We are extremely excited to complete this important safety study that will ultimately lead to the filing of our US IND.”

Mark DiNubile, MD, Chief Medical Officer, commented, “We are extremely pleased to report that cohort 4 used the highest dose ever administered to patients and no safety signals were observed at any dosing level. Now that our dose-finding trial is wrapping up, we look forward to our pivotal Phase 2b/3 study in CAP and then beyond to other infectious and non-infectious inflammatory indications.”

Plasma Gelsolin

Plasma gelsolin is an abundant circulating protein that enhances macrophage antimicrobial activity, limits the excessive spread of inflammation, and dissolves biofilm that accumulates around damaged cells. Decreased plasma gelsolin levels at presentation are not only found in CAP patients, but also in patients with diverse infectious and non-infectious inflammatory diseases, who are at high risk for developing serious complications.

About BioAegis Therapeutics

BioAegis Therapeutics Inc. is a clinical stage, private company whose mission is to exploit a key component of the body’s innate immune system to prevent adverse outcomes in diseases driven by inflammation and infection. BioAegis’ platform of opportunities exploits the multifunctional role of plasma gelsolin, a highly conserved, endogenous human protein.

*https://clinicaltrials.gov/ct2/show/NCT03466073

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