



BioAegis Therapeutics Reports Favorable Safety and Pharmacokinetic Results in its Phase 1b/2a Dose-Escalation Study of Recombinant Human Plasma Gelsolin with Highest Doses Ever Administered to Patients

MORRISTOWN, N.J., Aug. 07, 2019 (GLOBE NEWSWIRE) -- BioAegis Therapeutics, Inc. announced the major findings from its Phase 1b/2a study of Recombinant Human Plasma Gelsolin for patients requiring hospitalization because of Community-Acquired Pneumonia.

This blinded placebo-controlled trial was a dose-escalation study with four cohorts of 8 patients randomized 3:1 to recombinant gelsolin versus placebo. The highest-dose cohort receive 3 consecutive daily doses of 24 milligrams per kilogram of body weight. As anticipated, no serious or drug-related adverse events were reported in what were the highest doses ever administered to patients. Furthermore, analysis of the pharmacokinetics demonstrated that the product half-life exceeded 12 to 16 hours which supports once-daily dosing.

Clean Safety Profile Even at Supra-Physiologic Levels

No safety signals were uncovered. Patients in the higher dose cohorts received doses of plasma gelsolin that pushed their plasma gelsolin levels to higher than normal. Even with supra-physiologic levels, neither serious nor drug-related adverse events were reported in these patients.

Some Improvement in Markers of Inflammation Seen

Although the study was neither designed nor powered to demonstrate efficacy, a detailed analysis of the data revealed some improvement in pro-inflammatory markers among the recombinant gelsolin-treated patients. This observation is consistent with what has been demonstrated in animal models of various disease conditions.

Plasma Gelsolin

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

BioAegis' Novel Approach Offers an Innovative Treatment Paradigm With Broad Therapeutic Application in Diseases Driven by Inflammation.

Severe community-acquired pneumonia 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. Low levels of plasma gelsolin have consistently been shown to predict adverse outcomes in patients with inflammatory disease. The therapeutic efficacy of supplementation with recombinant gelsolin has been consistently demonstrated in greater than 25 infectious and non-infectious animal models of common inflammatory conditions. **Due to its enhancement of the response to pathogens and benign safety profile, it is not immunosuppressive, unique properties for an anti-inflammatory approach.**

Susan Levinson, PhD, Chief Executive Officer of BioAegis stated, "We are extremely pleased these results matched our expectations that this naturally occurring protein can be safely administered. We will now move forward with our plans to demonstrate clinical benefit in patients at risk for serious adverse outcomes."

Mark DiNubile, MD, Chief Medical Officer, commented, "These results allow us to move forward into a Phase 2b/3 study in Community-Acquired Pneumonia and beyond to other infectious and non-infectious inflammatory indications."

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, filling a major gap in current treatment of inflammatory disease... controlling excess inflammation without suppressing the immune response to threats. BioAegis' platform of opportunities exploits the multifunctional role of plasma gelsolin, a highly conserved, endogenous human protein.

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

This press release contains express or implied forward-looking statements, which are based on current expectations of management. These statements relate to, among other things, our expectations regarding management's plans, objectives, and strategies. These statements are neither promises nor guarantees but are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in these forward-looking statements. BioAegis assumes no obligation to update any forward-looking statements appearing in this press release in the event of changing circumstances or otherwise, and such statements are current only as of the date they are made.

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