BioAegis Therapeutics Expands Phase 1b/2a Community-Acquired Pneumonia Study to the Republic of Georgia — Successfully Completes Second of Four Dosing Cohorts

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MORRISTOWN, N.J., Feb. 07, 2019 (GLOBE NEWSWIRE) -- BioAegis Therapeutics Inc. announced that patient enrollment is underway in a Phase 1b/2a study of recombinant plasma gelsolin (rhu-pGSN) in Community-Acquired Pneumonia (CAP) in the Republic of Georgia. The clinical-stage company is focused on a novel approach to address infectious, inflammatory and degenerative diseases through a portfolio built around the supplementation of plasma gelsolin levels. The Data Safety Monitoring Board (DSMB) met on 25 Jan 2019 to review the safety data for the 6 mg/kg multiple dose level (cohort 2). Review of the safety data did not reveal any safety concerns and accordingly the DSMB recommended to start enrollment into the 12 mg/kg multiple ascending dose level (cohort 3).

Severe CAP is a leading cause of death in the US and around the world. According to the **American Thoracic Society**, mortality due to pneumonia has not changed in the US since antibiotics first became widely available more than a half a century ago. Significant numbers of CAP patients develop short- and long-term complications, placing a significant burden on the health care system. Survivors often require ongoing care for lingering neurocognitive and functional disabilities even after being discharged from the hospital.

BioAegis, together with Investigators at **Vanderbilt** and **Northwestern Universities** along with CDC scientists had previously demonstrated in human samples that patients admitted to the hospital with Community-Acquired Pneumonia have depressed levels of plasma gelsolin at presentation and that the extent of this depression predicts subsequent adverse outcomes.

Therapeutic efficacy of rhu-pGSN supplementation has been consistently demonstrated in greater than 25 infectious and non-infectious disease animal models. **Moreover, due to its**

host-based mechanism, rhu-pGSN has further demonstrated effectiveness against both gram-positive and gram-negative infection, including pathogens resistant to multiple antibiotics.

Susan Levinson, PhD, Chief Executive Officer of BioAegis stated, “We are very pleased with the professionalism of our Georgian collaborators and the speed and efficiency in opening sites and enrolling patients.”

Mark DiNubile, MD, Chief Medical Officer, commented, “Harnessing the body’s immune system offers a safe, powerful approach that can lead to more effective therapies for serious infectious and non-infectious inflammatory diseases. We eagerly look forward to successfully completing the remaining 2 cohorts in our dose-finding safety trial.”

Plasma Gelsolin

Plasma gelsolin (pGSN) is an abundant circulating protein that enhances macrophage antimicrobial activity, limits the excessive spread of inflammation, and neutralizes actin exposed by damaged cells. Decreased pGSN 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 harness the body’s innate immune system to address adverse outcomes in diseases driven by inflammation and infection. BioAegis’ platform of opportunities exploits the multifunctional role of plasma gelsolin (pGSN), 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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