Noveome Biotherapeutics Completes Dosing of First Baby in Clinical Trial for Treatment of Necrotizing Enterocolitis

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PITTSBURGH, PA, UNITED STATES, November 14, 2024 / EINPresswire.com/ -- Noveome Biotherapeutics, Inc., a clinical stage Pittsburgh-based biopharmaceutical company focused on developing next-generation biologics for the treatment of rare pediatric diseases with high morbidity and mortality, today announced that it has completed treatment of the first baby in its Phase 1-2 clinical trial evaluating the safety and efficacy of its novel biologic ST266 in Necrotizing Enterocolitis (NEC).

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> *Dr. Karin Potoka, Chief Medical Officer*

The NEC Bell Stage 2a-diagnosed baby completed 10 days of treatment, as well as the required 2-week and 1-month post-treatment follow-up visits. The ST266 infusion was well tolerated, with no vital sign irregularities during or after treatment, no infusion site reactions, no systemic adverse reactions and no adverse effects related to the treatment. Following a 1-month post-treatment follow-up visit, the Data Safety Monitoring Board (DSMB), composed of three board-certified neonatologists and one biostatistician independent of the study, reviewed all the data. The DSMB reported that the study may continue without modification.

Provided no safety issues arise after each of the first three babies are dosed and following a one month waiting period, all six sites in the study will be able to simultaneously enroll to accelerate the speed of recruitment. The clinical trial is expected to enroll approximately 36 babies diagnosed with NEC. 24 babies will be randomized to receive ST266 in addition to standard of care and 12 will be randomized to receive standard of care only. NEC-diagnosed babies in the

treatment group will be treated with intravenously administered ST266 once daily for 10 days. Key endpoints are intended to demonstrate safety and tolerability as well as to assess preliminary efficacy by evaluating clinical outcomes such as time to resolution of pneumatosis, time to return to full feeding, reduction of surgical intervention, and effect on long term neurodevelopment outcomes.

“NEC is an often-fatal inflammatory gastrointestinal disease that can develop in premature infants,” said Dr. Karin Potoka, Chief Medical Officer of Noveome. “There are currently no pharmacological therapies approved specifically for the treatment of NEC, making it a major unmet need globally.”

“We are excited with our very preliminary NEC safety results and look forward to enrolling more babies at all of the study sites. We are also pleased with other important progress made across numerous business functions in support of future Noveome commercialization goals.” said Pat Welch, Noveome CEO.

About ST266
ST266 is a cell-free sterile biologic solution containing hundreds of proteins and other factors at physiologic levels. It is made by culturing a novel population of human amnion-derived cells. Using a proprietary culturing method, these cells produce a unique array of growth factors and cytokines, known as the secretome, which promote cellular survival and reduce inflammation. Extensive preclinical studies have shown that ST266’s multiple components result in a variety of anti-inflammatory and neuroprotective responses. A drug master file has been submitted to the FDA, supporting all ST266 investigational new drug (IND) applications.

About Necrotizing Enterocolitis
Necrotizing Enterocolitis (NEC) is a devastating disease caused by infection and inflammation of the intestines observed primarily in premature and very low birth weight babies (VLBWB). The localized inflammation can result in loss of bowel wall integrity and overwhelming sepsis which quickly becomes a medical emergency and often requires surgery as a life-saving measure. Necrotizing enterocolitis affects 2% to 10% of all premature infants worldwide. Currently, one baby in the US dies every day from NEC. Treating and managing premature infants with NEC is responsible for over $5 billion annually in Neonatal Intensive Care Unit (NICU) expenditures in the United States. Babies that do survive can be left with life-long intestinal complications and a significant proportion of babies have neurodevelopmental delays including cognitive, visual, and motor impairments.

About Noveome Biotherapeutics, Inc.
Based in Pittsburgh, Noveome Biotherapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing next-generation biologics for a wide range of indications including for the treatment of rare pediatric diseases with high morbidity and mortality. Noveome has completed a Phase 2 open-label clinical trial that demonstrated the benefit ST266 had in healing persistent corneal epithelial defects (PEDs). ST266 also completed a Phase 1 open-

label clinical trial establishing the safety of ST266 in intranasal transcribriform delivery from nose-to-brain and eye, and a Phase 1 clinical trial establishing the safety of intravenously administered ST266 in COVID-19 patients. The FDA has previously granted both Rare Pediatric Disease Designation (RPDD) and Orphan Drug Designation (ODD) to ST266 for the treatment of NEC. For more information, visit www.noveome.com.

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