

Noveome Biotherapeutics, Inc. Completes First Close of \$40 Million Series E Financing to Support Clinical Trials in NEC

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PITTSBURGH, PA, UNITED STATES, August 17, 2023 /EINPresswire.com/ --Noveome Biotherapeutics, Inc.



Completes First Close of \$40 Million Series E Financing to Advance Growing Pipeline of Next-Generation Biologics and Support Clinical Trials Evaluating ST266 in Necrotizing Enterocolitis

Pre-clinical results suggest that ST266 may be effective in both preventing and treating



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Patrick Welch

Necrotizing Enterocolitis; first potential breakthrough therapy in over 30 years

Noveome Biotherapeutics, Inc., a Pittsburgh-based biopharmaceutical company in clinical-stages focused on developing next-generation biologics for the promotion and restoration of cellular integrity of inflamed or damaged tissues, today announced a \$20.7 million first tranche closing of a total \$40.2 million Series E financing. The financing was led by MAK Capital, along with additional investment from existing investors. Prior to this Series E financing, Noveome has raised a total of \$170 million from

both private investors and non-dilutive financing from the U.S. Department of Defense and the Commonwealth of Pennsylvania and Allegheny County. The Company expects to complete the Series E financing by December 31, 2023.

Proceeds from the financing will be primarily used to support the advancement of the Company's clinical stage program investigating its proprietary, cell-free platform biologic, ST266, for the treatment of Necrotizing Enterocolitis (NEC), a rare pediatric disease. ST266 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. NEC is an often-fatal inflammatory gastrointestinal disease that can develop in premature infants. The U.S. Food and Drug Administration (FDA) has previously granted Rare Pediatric Disease Designation (RPDD) and Orphan Drug Designation (ODD) to the Company's lead product ST266 for the treatment of NEC.

"NEC is a devastating disease that affects the most vulnerable among us," said Patrick Welch, Chief Executive Officer of Noveome. "We are encouraged by the support from both MAK and existing investors in this Series E financing, providing Noveome with the necessary funding to progress our clinical stage NEC program."

"We are excited to join Noveome and support the broad therapeutic potential of ST266 to deliver novel treatments to patients suffering from a wide variety of complex diseases," added Michael Kaufman, CEO of MAK Capital. "We are motivated by the prospect of providing the first major improvement in lifesaving therapy for infants affected by NEC in over 30 years."

"The previously published preclinical studies (Am J Physiol Gastrointest Liver Physiol. 2022 Sep 1;323(3):G265-G282. (https://pubmed.ncbi.nlm.nih.gov/35819175/) suggest that ST266 could be useful in the prevention or treatment of clinical NEC, and support initiating a Phase 1-2 clinical trial to further assess ST266's safety, tolerability and preliminary efficacy in this indication," said Larry Brown, Sc.D., Executive Vice President and CSO of Noveome. Dr. Brown continued, "No approved therapeutic agent has been developed for NEC in over 30 years and we are excited about the potential for ST266 to revolutionize both prevention and treatment of this devastating disease."

About ST266

ST266 is a cell-free sterile biologic solution containing hundreds of proteins and other factors at physiologic levels. 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 inflammation of the intestines observed primarily in premature and very low birth weight babies (VLBWB). The inflammation can result in an overwhelming infection which quickly becomes a medical emergency and often requires surgery as a life-saving measure. NEC affects between 4,000 – 6,000 VLBWB each year in the United States and carries a 30% mortality rate. Babies that do survive are often left with lifelong intestinal complications and are also at increased risk for neurodevelopmental delay with cognitive, visual, and motor impairment. Treating and managing NEC costs over \$5 billion annually in Neonatal Intensive Care Unit (NICU) expenditures.

There is currently no FDA-approved treatment for NEC.

About Noveome Biotherapeutics, Inc.

Based in Pittsburgh, Noveome Biotherapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing next-generation biologics for the promotion and restoration of cellular integrity of inflamed or damaged tissues. 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. For more information, visit www.noveome.com.

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