Novoclem Therapeutics, Inc. Receives QIDP Status for Its Lead Inhaled Antimicrobial Drug Candidate

DURHAM, NC (November 7, 2017) – Novoclem Therapeutics, Inc., today announced that its lead inhaled antimicrobial drug candidate, BIOC51, has been designated as a "Qualified Infectious Disease Product" (QIDP) by the U.S. Food & Drug Administration. The QIDP designation, granted for treatment of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis, will make BIOC51 eligible to benefit from certain incentives for the development of new antibiotics provided under the Generating Antibiotic Incentives Now Act (GAIN Act). These incentives include priority review and eligibility for fast-track status. Further, if ultimately approved by the FDA, BIOC51 is eligible for an additional five-year extension of market exclusivity.

"We are very pleased that the FDA has granted QIDP designation to BIOC51," said Anne Whitaker, Chief Executive Officer of Novoclem Therapeutics. "Chronic, persistent lung infections with *Pseudomonas aeruginosa* are a major factor impacting the poor quality of life and untimely death in cystic fibrosis patients. The QIDP designation will accelerate the advancement of BIOC51 development as a potential treatment for these patients."

About BIOC51
BIOC51 is a novel polyglucosamine biopolymer covalently modified with N-diazeniumdiolate nitric oxide (NO) donors to facilitate spontaneous (without the need of enzymes) and controlled NO release. The level of NO release from BIOC51 has proved sufficient for eradacting planktonic and biofilm-based bacteria, and can be delivered to the lungs as a dry powder or solution (e.g., nebulization).

About Cystic Fibrosis
Cystic Fibrosis (CF) is a rare life-threatening hereditary disease characterized by the production of thick, hard to clear mucus within the lung, leading to recurrent lung infections and loss of lung function. Antibiotic therapy, routinely used to treat lung infections in people with CF, becomes ineffective as bacterial resistance develops. The thick mucus within the lungs also makes it difficult for antibiotics to penetrate bacterial colonies so there is a great need to develop alternative agents that can treat bacterial infection in people with CF.

About Novoclem Therapeutics, Inc.
Novoclem Therapeutics, Inc., a subsidiary of KNOW Bio, LLC, is an innovative, preclinical-stage pharmaceutical company focused on helping people who suffer from severe respiratory diseases to breath better and live life more fully. It is initially focused on developing a nitric oxide based treatment for people living with cystic fibrosis and infected with *Pseudomonas aeruginosa*. The company anticipates submitting an Investigational New Drug application and initiating First in Human clinical trials in 2018. More info available at www.novoclem.com.

About the GAIN Act
The GAIN Act, Title VIII (Sections 801 through 806) of the FDA Safety and Innovation Act, seeks to provide pharmaceutical and biotechnology companies with incentives to develop new antibacterial and antifungal drugs for the treatment of life-threatening, infectious diseases caused by drug resistant pathogens. Qualifying pathogens are defined by the GAIN Act to include multi-drug resistant Gram-negative bacteria, including *Pseudomonas*, *Acinetobacter*, *Klebsiella*, and *Escherichia coli* species. It extends the length of time an approved drug is free from competition and clarifies the regulatory pathway for new antibiotics.

About KNOW Bio LLC
KNOW Bio, LLC, is a life science company committed to improving and extending people's lives by advancing the development and commercialization of its drug and device pipeline through wholly or majority owned subsidiary companies. Each subsidiary is focused on a specific therapeutic application where nitric oxide provides meaningful health benefit.

Forward-looking Statements
Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. Actual results might differ materially from those explicit or implicit in the forward-looking statements. Important factors that could cause actual results to differ materially include: risks associated with the drug development process; reliance on key personnel; the early stage of our business; competition; and other risks described in other Company press releases and presentations. KNOW Bio and Novoclem Therapeutics assume no obligation and do not intend to update these forward-looking statements, except as required by law.

Media Contact:
Darlene Dendy, Director of Administration
1-919-270-5789
ddendy@novoclem.com