



4222 Emperor Blvd., Suite 470 Durham, NC 27705

Vast Therapeutics Receives Qualified Infectious Disease Product Status for BIOC11

Second Drug Candidate to Receive QIDP Designation for Vast

DURHAM, NC – October 8, 2019 – Vast Therapeutics, Inc., a subsidiary of KNOW Bio, LLC, today announced that another of its drug candidates, BIOC11, has been designated as a “Qualified Infectious Disease Product” (QIDP) by the U.S. Food and Drug Administration. Vast is a preclinical-stage pharmaceutical company focused on treating respiratory infections through the power of nitric oxide (NO) in a synthetically derived powder-based form. The QIDP designation, granted for treatment of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis, will make BIOC11 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, BIOC11 is eligible for an additional five-year extension of market exclusivity.

“We are very pleased that the FDA has granted QIDP designation to BIOC11,” said Mark Schoenfisch, President and CSO of Vast Therapeutics. “BIOC11 reflects an advanced platform for the delivery of nitric oxide and demonstrates that our nitric oxide-releasing pipeline is deep with additional candidates. Chronic, persistent lung infections continue to increase in frequency and are a major factor impacting the quality of life and untimely mortality of patients across a broad spectrum of diseases. The QIDP designation will accelerate the advancement of BIOC11 regulatory approval as a potential treatment for these patients.”

The QIDP designation was created by the Generating Antibiotic Incentives Now (GAIN) Act and creates incentives for the development of certain antibiotics that treat serious or life-threatening infections. The primary incentives are an additional five-year extension of Hatch-Waxman Act exclusivity, as well as priority FDA review of the first marketing application or efficacy supplement for BIOC11 and the indication for the QIDP designation with an opportunity to request Fast Track designation for BIOC11

“The designation of BIOC11 to QIDP status is yet another achievement for Vast and the KNOW Bio group,” said Neal Hunter, CEO and Chairman of the Board of Vast Therapeutics and Managing Director of KNOW Bio, LLC. “This designation for a new materials system underscores our commitment to foundational drug product technology. The QIDP success should decrease the timeline to serve our patients and deliver value to our shareholders.”

Vast Therapeutics is based in the Research Triangle Park area of North Carolina and runs a leveraged drug development model using a small team with high quality service contractors and suppliers.



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About Vast Therapeutics, Inc.

Vast Therapeutics, 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. The Company is initially focused on developing a nitric oxide-based drug to treat cystic fibrosis patients battling chronic *Pseudomonas aeruginosa* infections. The Company anticipates submitting an investigational New Drug application and initiating First-in-Human clinical trials in 2019. More info available at www.vasttherapeutics.com.

About Mark Schoenfisch, PhD

Mark Schoenfisch, PhD is President and Chief Scientific Officer of Vast Therapeutics and a Professor of Chemistry at the University of North Carolina at Chapel Hill. Mark is an active entrepreneur and the inventor of multiple macromolecular nitric oxide-release systems, guiding technologies from research discoveries to manufacturing and clinical trials. With 20 years of experience working with nitric oxide chemistry, Mark has published more than 100 peer-reviewed articles describing the synthesis, characterization, and application of nitric oxide-modified biomaterials. Prior to his current role, Mark co-founded Novan, Inc., where he helped guide the company to its IPO as a member of its Board of Directors.

About Neal Hunter

Neal Hunter is CEO and Chairman of the Board of Vast Therapeutics, Inc. and Managing Director of KNOW Bio, LLC. Prior to his current roles, Neal developed a 25-year track record of successfully raising capital for and building technology companies in the public and private markets, including co-founding Cree, Inc. and LED Lighting Fixtures, Inc. Neal also served as co-founder, co-founding investor or founding investor in over ten significant start-up ventures in the areas of semiconductor materials and devices, aesthetic materials, software, commercial and residential real estate, LED lighting systems and life sciences, where he developed his proven expertise in technology transfer, from inception of innovations to the creation of market-changing products.

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 and our need to raise additional capital to complete development of our drug candidates; competition; and other risks described in other Company press releases and presentations. KNOW Bio and VAST Therapeutics assumes no obligation and does not intend to update these forward-looking statements, except as required by law.



VAST THERAPEUTICS

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