Entasis Therapeutics Initiates Global Phase 3 Pivotal Trial of ETX2514SUL for Patients with Carbapenem-Resistant Acinetobacter Infections

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WALTHAM, Mass., April 04, 2019 (GLOBE NEWSWIRE) -- Entasis Therapeutics Holdings Inc. (NASDAQ: ETTX), a clinical-stage biopharmaceutical company developing novel antibacterials to treat serious drug-resistant infections, today announced the initiation of the ATTACK (Acinetobacter Treatment Trial Against Colistin) Phase 3 pivotal clinical trial to evaluate ETX2514SUL, a fixed-dose combination of its broad-spectrum β-lactamase inhibitor ETX2514 with sulbactam, for the treatment of patients with pneumonia and bloodstream infections caused by carbapenem-resistant Acinetobacter baumannii.

A. baumannii is a Gram-negative bacterium that causes severe infections and is associated with high mortality, increasing rates of antibiotic resistance and growing significance as a hospital-acquired infection due to limited treatment options. Outbreaks of A. baumannii typically occur in intensive care units and healthcare settings with seriously ill patients, and can either cause or contribute to death. Resistance to carbapenems, a class of antibiotics commonly used for the treatment of severe bacterial infections, has grown substantially amongst Acinetobacter in the last decade, resulting in a significant unmet medical need.

“There are currently very limited antibiotic choices for the treatment of multidrug-resistant A. baumannii infections, and mortality rates approach 50%,” said Robin Isaacs, MD, Chief Medical Officer. “More than 60% of A. baumannii strains tested in the United States in 2016 were resistant to carbapenems, and in some European and Asian countries carbapenem resistance surpasses 80%. ETX2514SUL offers a precision, pathogen-targeted, approach to the treatment of A. baumannii. We look forward to enrolling patients in our ATTACK trial which will evaluate ETX2514SUL’s efficacy and safety in the treatment of drug-resistant A. baumannii infections.”

ATTACK is a global, two-part Phase 3 clinical trial that will enroll a total of 300 patients from 18 countries. The Company believes this single Phase 3 trial could be sufficient to support the filing of a new drug application with regulatory authorities in both the U.S. and Europe. Subject to necessary regulatory approvals, the clinical trial will also leverage the Company’s partnership with Zai Lab for patient enrollment in China, and potentially provide early access for patients in Asia-Pacific countries. The trial will also incorporate the BioFire® FilmArray® Pneumonia Panel to optimize and accelerate patient enrollment. For more information about the ATTACK trial, please visit www.clinicaltrials.gov (NCT03894046).

"We are excited to initiate our global ATTACK clinical trial with the ultimate goal of obtaining regulatory approval in the U.S. and other countries,” said Manos Perros, Chief Executive Officer, Entasis Therapeutics. “It is the culmination of extensive preclinical development and multiple Phase 1 and 2 clinical trials, which have shown that ETX2514SUL has great potential for the treatment of patients with carbapenem-resistant A. baumannii infections. We are fully funded through this study and look forward to reporting top-line data in the second half of 2020.”

The initiation of ATTACK follows the End-of-Phase-2 meeting with the U.S. Food and Drug Administration (FDA). ETX2514SUL has been designated a Qualified Infectious Disease Product (QIDP) by the U.S. FDA and granted Fast Track designation.

About ETX2514

ETX2514 is a novel, broad-spectrum inhibitor of class A, C, and D β-lactamases. ETX2514 restores the in vitro activity of multiple β-lactams against Gram-negative, multidrug-resistant (MDR) pathogens. Entasis Therapeutics is initially developing ETX2514SUL, the combination of ETX2514 and sulbactam, for the treatment of severe A. baumannii infections. Sulbactam is a generic β-lactam which has intrinsic antibacterial activity against A. baumannii but suffers from widespread β-lactamase-mediated resistance. In preclinical studies, ETX2514 restored sulbactam antibacterial activity against A. baumannii. ETX2514 has completed single- and multi-ascending dose Phase 1 trials and a Phase 2 trial, in combination with sulbactam, in complicated urinary tract infections.

About Entasis

Entasis is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel antibacterial products to treat serious infections caused by multidrug-resistant Gram-negative bacteria. Entasis’ targeted-design platform has produced a pipeline of product candidates, including ETX2514SUL (targeting A. baumannii infections), zoliflodacin

(targeting Neisseria gonorrhoeae), and ETX0282CPDP (targeting Enterobacteriaceae infections). Entasis is also using its platform to develop a novel class of antibiotics, non-β-lactam inhibitors of the penicillin-binding proteins (NBPs) (targeting Gram-negative infections). For more information, visit www.entasistx.com.

Entasis Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Entasis' expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements about (i) the timing of the initiation, progress and scope of the Phase 3 clinical trial of ETX2514SUL; (ii) the timing of the availability of data; (iii) design of the Phase 3 clinical trial of ETX2514SUL, including plans to incorporate BIOFIRE Instruments and Pneumonia Panels into this trial and their ability to optimize and accelerate patient enrollment; (iv) the success of the Phase 3 clinical trial of ETX2514SUL; (v) the sufficiency of the single trial to support the filing of an NDA with the FDA; and (vi) potential clinical benefits of ETX2514SUL. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during non-clinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected and changes in expected or existing competition. Except as required by law, Entasis assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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