Entasis Therapeutics Receives Positive Feedback from FDA End-of-Phase 2 Meeting for ETX2514SUL; Signs Rapid Diagnostic Agreement with bioMérieux

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Entasis to incorporate BIOFIRE® FILMARRAY® System, a rapid molecular diagnostic platform, into ETX2514SUL Phase 3 clinical trial, on track to initiate in 1Q 2019

WALTHAM, Mass., Feb. 05, 2019 (GLOBE NEWSWIRE) -- Entasis Therapeutics Holdings Inc. (NASDAQ: ETTX), a clinical-stage biopharmaceutical company focused on the discovery and development of novel antibacterial products, today announced a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding ETX2514SUL for the treatment of patients with pneumonia and bloodstream infections caused by carbapenem-resistant *Acinetobacter baumannii*. A Gram-negative bacterium causing severe infections, *A. baummanii* is associated with high mortality, rapidly-increasing rates of antibiotic resistance, growing significance as a hospital-acquired infection, and limited treatment options. Following this meeting, Entasis remains on track to initiate its Phase 3 clinical trial for ETX2514SUL in the first quarter of 2019.

Further, Entasis announced an agreement with bioMérieux, a world leader in the field of *in vitro* diagnostics, pursuant to which Entasis will incorporate BIOFIRE® FILMARRAY® Instruments and BIOFIRE® FILMARRAY® Pneumonia Panels into its global Phase 3 trial for ETX2514SUL for enrollment optimization. The BIOFIRE System is an FDA-cleared and CE-marked multiplex PCR system that integrates sample preparation, amplification, and detection into one closed system. The BIOFIRE System requires only two minutes of hands-on time and has a total run time of approximately 45 to 75 minutes, depending on the panel. The BIOFIRE Pneumonia Panel and the BIOFIRE® FILMARRAY®Pneumonia Panel*plus* received FDA clearance and CE-Marking in November 2018. The BIOFIRE Pneumonia Panels enable fast, accurate, and comprehensive syndromic testing for lower respiratory tract infections and can identify 33 targets, including *A. baumannii*, direct from sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL) sample types.

"We are extremely pleased with the outcome of our End-of-Phase 2 meeting with the FDA and excited to incorporate the BIOFIRE System into our Phase 3 clinical trial," said Robin Isaacs, Chief Medical Officer, Entasis Therapeutics. "With our successful FDA meeting and the incorporation of the BIOFIRE System into the trial for enrollment optimization, we have positioned ETX2514SUL for success as it enters its next phase of development."

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. The FDA has granted Qualified Infectious Disease Product (QIDP) designation and Fast Track status to ETX2514SUL for the treatment of hospital-acquired and ventilator-acquired bacterial pneumonia and bloodstream infections due to *A. baumannii*.

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) design of the Phase 3 clinical trial of ETX2514SUL, including plans to incorporate BIOFIRE Instruments and Pneumonia Panels into this trial; and (iii) the success of the Phase 3 clinical trial 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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