Entasis Announces Positive Phase 2 Data of ETX0914 for the Treatment of Gonorrhea

Validates Company’s Pathogen-targeted Discovery and Development Platform

WALTHAM, Mass. — September 21, 2016 — Entasis Therapeutics, a company focused on the discovery and development of breakthrough anti-infective products, today announced that data from a Phase 2 study of ETX0914, the Company’s novel oral antibiotic compound, will be presented at the 2016 STD Prevention Conference in Atlanta. Stephanie N. Taylor, M.D., Professor of Medicine & Microbiology at Louisiana State University Health Sciences Center and the trial's lead investigator, will present “A Phase II Trial of Single-Dose Oral ETX0914 (AZD0914) for Treatment of Uncomplicated Urogenital Gonorrhea” on Friday, September 23, 2016. The study was supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, through a contract to the University of Alabama. The University of Alabama is part of NIAID’s Sexually Transmitted Infections Clinical Trials Group.

The Phase 2 randomized, open-label study enrolled 179 patients (167 men and 12 women) with urogenital gonorrhea who were treated with ETX0914 alone (at either 2g or 3g dosage levels) or ceftriaxone alone. The study achieved its primary objectives, with all patients in the 3g ETX0914 arm (47/47) and 98 percent of patients in the 2g arm (48/49) cured of the infection. ETX0914 was well tolerated with a small number of patients (21/179) reporting side effects, which were mostly mild and primarily gastrointestinal.

Dr. Taylor noted, “Gonorrhea is a serious infection which can result in major consequences if left untreated. Resistance to current antibiotic treatments is on the rise, increasing the risk of untreatable gonorrhea in the U.S. and abroad. We are very pleased with these promising results which support the continued development of ETX0914 through further clinical studies.”

“ETX0914 is a novel oral antibiotic designed to be highly active against both the drug-sensitive and drug-resistant bacteria which cause gonorrhea,” said Manos Perros, Ph.D., President and Chief Executive Officer of Entasis. “This is the first of a number of exciting agents in our portfolio to be tested in a clinical setting. This strong Phase 2 data validates Entasis’ overarching mission of discovering and developing antibiotic treatments for serious drug-resistant infections using a pathogen-targeted approach.”

About ETX0914
ETX0914 is a novel oral antibiotic for the treatment of uncomplicated gonorrhea and the first of a novel class of molecules to be developed for this indication. Uncomplicated gonorrhea is becoming increasingly difficult to treat as the Neisseria gonorrhoeae bacterium has developed resistance to successive classes of antibiotics. There are currently few oral treatment options, and the Centers for Disease Control and Prevention has recently designated N. gonorrhoeae an urgent public health threat that requires aggressive action. N. gonorrhoeae has developed resistance to all classes of antimicrobials previously recommended for treatment of uncomplicated gonorrhea, leaving only one injectable cephalosporin, ceftriaxone, as a recommended first-line therapy.
Uncomplicated gonorrhea infections carry high morbidity, enhance transmission of other sexually transmitted diseases and are highly stigmatized. Published studies have demonstrated the potent *in vitro* activity of ETX0914 against *N. gonorrhoeae*, including isolates resistant to fluoroquinolones and extended spectrum cephalosporins. ETX0914 has been designated a Qualified Infectious Disease Product (QIDP) by the U.S. Food and Drug Administration and awarded a Fast Track status.

**About Entasis Therapeutics Inc.**
Entasis Therapeutics is developing a portfolio of innovative cures for serious drug-resistant bacterial infections, a global health crisis affecting the lives of millions of patients. Our deep pipeline of fundamentally innovative clinical and preclinical anti-infective programs is designed to revolutionize the way physicians treat serious bacterial diseases. [www.entasistx.com](http://www.entasistx.com)

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