November 17, 2016

Tetraphase Publishes Phase 3 IGNITE1 Eravacycline Data in JAMA Surgery

WATERTOWN, Mass., Nov. 17, 2016 (GLOBE NEWSWIRE) -- Tetraphase Pharmaceuticals, Inc. (NASDAQ:TTPH), a clinical stage biopharmaceutical company developing novel antibiotics to treat life-threatening multidrug-resistant (MDR) infections, today announced the publication of results from IGNITE1, the Company's phase 3 clinical trial which evaluated eravacycline compared to ertapenem for the treatment of complicated intra-abdominal infection (cIAI), in the *Journal of the American Medical Association (JAMA) Surgery*. The article, titled "IGNITE1: A Phase III, Randomized Multicenter Prospective Study to Assess the Efficacy and Safety of Eravacycline vs. Ertapenem in Complicated Intra-Abdominal Infections," is available online and will appear in a forthcoming print issue of the journal. In the trial, eravacycline was well tolerated and demonstrated statistical non-inferiority to ertapenem using the primary endpoint of clinical response at the test-of-cure (TOC) visit, under the guidance set by the Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

"The incidence of life-threatening infections caused by drug-resistant bacteria is increasing at alarming rates. Without the introduction of new antibiotics, a clear public health threat is evolving," said Joseph Solomkin, M.D., Professor Emeritus in the Department of Surgery at the University of Cincinnati College of Medicine, and lead author of the *JAMA* paper. "These published data demonstrate eravacycline's ability to cure these infections as a monotherapy because of its activity against Gram-positive, Gram negative and anaerobic bacteria, including those resistant to commonly used antibiotics. These data support its potential as a novel antibiotic treatment option for serious intra-abdominal infections."

"The positive results from IGNITE1 demonstrate that treatment with eravacycline could fill an unmet need in patients with cIAI, particularly those with difficult-to-treat infections," said Guy Macdonald, President and CEO of Tetraphase. "These results, along with those from our ongoing phase 3 IGNITE4 trial in cIAI, which are expected in the fourth quarter of 2017, will form the basis of a New Drug Application submission for eravacycline in cIAI."

About IGNITE1
IGNITE1 was a randomized, multi-center, double-blind, double-dummy, global phase 3 clinical trial designed to assess the efficacy and safety of eravacycline, dosed intravenously 1 mg/kg every 12 hours, compared with ertapenem, dosed intravenously 1 g every 24 hours, for four up to 14 days. Per the trial design, 541 adult patients were enrolled in the trial at 66 centers worldwide. Under the guidance set by the FDA and the EMA, the primary endpoint of the trial was clinical response at TOC visit, which took place 25 to 31 days after the initial study drug dose, in the two treatment arms. For the FDA, the primary analysis was conducted using a 10% non-inferiority margin in the microbiological intent-to-treat (micro-ITT) population. For the EMA, the primary analysis was conducted using a 12.5% non-inferiority margin in the all-treated (MITT) and clinically evaluable (CE) patient populations.

In the IGNITE1 study, in the micro-ITT population, the lower and upper bounds of the 95% confidence interval were -7.1% and 5.5%, respectively. In the MITT and CE populations, the lower and upper bounds of the 99% confidence interval were -9.2% and 5.6%; and -7.9% and 4.4%, respectively. Eravacycline demonstrated high clinical cure rates against Gram-negative pathogens, including those that were carbapenem-resistant, 3rd/4th generation cephalosporin-resistant, or multidrug-resistant.

About IGNITE4
IGNITE4 is a phase 3 randomized, double-blind, double-dummy, multicenter, prospective study that is designed to assess the efficacy, safety and pharmacokinetics of twice-daily eravacycline (1 mg/kg every 12 hours) compared with meropenem (1 g every 8 hours) for the treatment of cIAI. The study is expected to enroll approximately 450 adult patients at 75 centers worldwide. Per agreement with the FDA and EMA, the primary endpoint of IGNITE4 is clinical response at the TOC visit, which will be analyzed using a 12.5% non-inferiority margin. The primary analysis populations will be the micro-ITT population for the FDA and the MITT and CE populations for the EMA.

About Eravacycline
Eravacycline is a novel, fully-synthetic tetracycline antibiotic being developed for the treatment of serious infections, including those caused by multidrug-resistant (MDR) pathogens that have been highlighted as urgent public health threats by both the World Health Organization and the U.S. Centers for Disease Control (CDC). Eravacycline is Tetraphase's lead product candidate in phase 3 clinical development for the treatment of complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI).

Eravacycline is currently being investigated in the Company's phase 3 IGNITE (**I**nvestigating **G**ram-**n**egative **I**nfections **T**reated with **E**ravacycline) program. To date, eravacycline has been tested in over 1,300 patients and has been tested in

two completed phase 3 trials - IGNITE1 in patients with cIAI and IGNITE2 in patients with cUTI. In IGNITE1, twice-daily IV eravacycline met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to ertapenem, was well tolerated, and achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates. Tetraphase is currently evaluating eravacycline in a second phase 3 clinical trial in patients with cIAI (IGNITE4) comparing twice-daily IV eravacycline to meropenem. Assuming a positive outcome in IGNITE4, the Company plans to use the results from IGNITE1 and IGNITE4 to support an NDA submission for IV eravacycline for the treatment of patients with cIAI. The Company plans to initiate IGNITE3, an additional phase 3 trial evaluating once-daily IV eravacycline in patients with cUTI. Assuming a positive outcome, the Company plans to use the results from IGNITE3 to support a supplemental NDA (sNDA) submission for eravacycline in cUTI. In parallel, Tetraphase is continuing its efforts to develop an oral dose formulation of eravacycline. A phase 1 clinical program is ongoing which is designed to evaluate and optimize the oral dosing regimen for eravacycline.

About Tetraphase Pharmaceuticals, Inc.
Tetraphase is a clinical-stage biopharmaceutical company using its proprietary chemistry technology to create novel antibiotics for serious and life-threatening bacterial infections, including those caused by many of the multidrug-resistant (MDR) bacteria highlighted as urgent public health threats by the CDC. Tetraphase has created more than 3,000 novel tetracycline analogs using its proprietary technology platform. Tetraphase's pipeline includes three antibiotic clinical candidates: eravacycline, which is in phase 3 clinical trials, and TP-271 and TP-6076, which are in phase 1 clinical trials. Please visit www.tphase.com for more company information.

Forward-Looking Statements
Any statements in this press release about our future expectations, plans and prospects, including statements regarding our strategy, future operations, prospects, plans and objectives, and other statements containing the words "anticipates," "believes," "expects," "plans," "will" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether results obtained in early or interim clinical trials will be indicative of results obtained in future clinical trials; whether eravacycline or any other clinical candidate will advance through the clinical trial process on a timely basis; whether the results of the Company's trials will warrant regulatory submission and regulatory approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if any clinical candidate obtains approval, it will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of our quarterly report on Form 10-Q, filed with the Securities and Exchange Commission on November 3, 2016. In addition, the forward-looking statements included in this press release represent our views as of November 17, 2016. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so.

Investor Contacts:

Tetraphase Pharmaceuticals

Teri Dahlman

617-600-7040

tdahlman@tphase.com

Argot Partners

Maeve Conneighton

212-600-1902

maeve@argotpartners.com

Media Contact:

Sam Brown Inc.

Mike Beyer

312-961-2502

mikebeyer@sambrown.com

Primary Logo

Source: Tetraphase Pharmaceuticals

News Provided by Acquire Media