December 19, 2016

Tetraphase Pharmaceuticals Provides Regulatory and Clinical Update for Eravacycline

- Company to Submit MAA for Eravacycline for the Treatment of Complicated Intra-Abdominal Infections to the EMA in Second Half of 2017 -

- Phase 3 IGNITE3 Study in Complicated Urinary Tract Infections to Commence in First Quarter of 2017 -

WATERTOWN, Mass., Dec. 19, 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 provided a regulatory and clinical development update for eravacycline, the Company's lead antibiotic candidate with potent activity against MDR pathogens, which is being developed for the treatment of serious and life-threatening bacterial infections.

Intravenous (IV) Eravacycline for the Treatment of Complicated Intra-Abdominal Infections (cIAI)

During the second half of 2017, Tetraphase plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for IV eravacycline for the treatment of cIAI. The MAA submission will be supported by data from IGNITE1, the Company's successfully completed phase 3 clinical trial which evaluated the efficacy and safety of twice-daily IV eravacycline for the treatment of cIAI. In this study, eravacycline was well tolerated, met the FDA and EMA primary efficacy endpoints and achieved high cure rates, including in those patients with resistant and MDR Gram-negative pathogens.

In addition to IGNITE1, eravacycline is currently being evaluated in IGNITE4, a phase 3 clinical trial assessing the efficacy and safety of twice-daily IV eravacycline compared to meropenem in cIAI. As previously stated, Tetraphase expects to report top-line data from IGNITE4 during the fourth quarter of 2017. Assuming a successful outcome from IGNITE4, these data, along with data from IGNITE1, will support an NDA filing to the FDA for IV eravacycline in cIAI.

"Establishing a definitive timeline for an MAA filing in Europe, the first regulatory filing for IV eravacycline as a potential new treatment for cIAI, represents an important milestone for Tetraphase," said Guy Macdonald, President and CEO. "We also look forward to reporting top-line results from IGNITE4 in cIAI in the fourth quarter of 2017, followed by an NDA submission. We believe pursuing approval first in cIAI in both the U.S. and Europe is the fastest and most efficient way to get eravacycline into the hands of the physicians who want it, and, ultimately, the patients who need it."

IV Eravacycline for the Treatment of Complicated Urinary Tract Infections (cUTI)

During the first quarter of 2017, the Company plans to initiate IGNITE3, a randomized, multi-center, double-blind, phase 3 clinical trial evaluating the efficacy and safety of once-daily IV eravacycline (1.5mg/kg every 24 hours) compared to ertapenem (1g every 24 hours) for the treatment of complicated urinary tract infections (cUTI). IGNITE3 is expected to enroll approximately 1000 patients who will be randomized 1:1 to receive eravacycline or ertapenem for a minimum of 5 days, and will then be eligible to switch to oral therapy. The co-primary endpoints of responder rate (a combination of clinical cure rate and microbiological response) in the microbiological intent-to-treat (micro-ITT) population at the end-of-IV treatment visit and at the test-of-cure visit (Day 5-10 post therapy) will be evaluated using a 10% non-inferiority margin.

Oral Eravacycline Development Program

In parallel with the clinical trials using IV eravacycline, Tetraphase is continuing the development program for oral eravacycline. As previously reported, Tetraphase recently completed phase 1 clinical testing which suggests that fasted state administration of oral eravacycline results in increased drug exposure. Further clinical tests designed to evaluate other important variables are currently ongoing, with the goal of optimizing the oral eravacycline dosing regimen. The company expects to provide an update with top-line findings from this testing and potential next steps during the third quarter of 2017.

"With plans to begin IGNITE3 in the first quarter and to provide an update on the oral eravacycline development program during the third quarter, we look forward to sharing updates throughout the coming year," Mr. Macdonald continued. "As we look ahead to an event-driven 2017, we are focused on executing these strategic drivers and catalysts for the eravacycline development program."

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 1.0 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 IGNITE3
IGNITE3 is a phase 3 randomized, double-blind, multi-center, clinical trial evaluating the efficacy and safety of once-daily eravacycline (1.5mg/kg every 24 hours) compared to ertapenem (1g every 24 hours) for the treatment of cUTI. IGNITE3 is expected to enroll approximately 1000 patients who will be randomized 1:1 to receive eravacycline or ertapenem for a minimum of 5 days, and will then be eligible to switch to oral therapy. The co-primary endpoints of responder rate (a combination of clinical cure rate and microbiological response) in the micro-ITT population at the end-of-IV treatment visit and at the test-of-cure visit (Day 5-10 post therapy) will be evaluated using a 10% non-inferiority margin.

About IGNITE4
IGNITE4 is a phase 3 randomized, double-blind, double-dummy, multi-center clinical trial evaluating the efficacy, safety and pharmacokinetics of twice-daily eravacycline (1.0 mg/kg every 12 hours) compared with meropenem (1g every 8 hours) for the treatment of cIAI. The study is expected to enroll approximately 450 adult patients at 75 centers worldwide. The primary endpoint of IGNITE4 is clinical response at the test-of-cure (TOC) visit, which occurs 25 to 31 days after the initial dose of the study drug. The primary efficacy analysis will be conducted using a 12.5% non-inferiority margin in the microbiological intent-to-treat (micro-ITT) population.

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).

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 December 19, 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.

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Source: Tetraphase Pharmaceuticals

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