Tetraphase Announces Top-Line Results from IGNITE3 Phase 3 Clinical Trial of Eravacycline in Complicated Urinary Tract Infections (cUTI)

February 13, 2018

? Eravacycline Did Not Achieve Co-Primary Endpoints in cUTI Trial ?

? Company Continues to Prepare for Commercialization of Eravacycline as a Treatment for cIAI in the U.S. and Europe, Assuming Regulatory Approval ?

? Conference Call Scheduled for Today at 4:30 p.m. ET ?

WATERTOWN, Mass., Feb. 13, 2018 (GLOBE NEWSWIRE) -- Tetraphase Pharmaceuticals, Inc. (NASDAQ:TTPH), a biopharmaceutical company focused on developing and commercializing novel antibiotics to treat life-threatening multidrug-resistant (MDR) infections, today announced that its IGNITE3 clinical trial evaluating the efficacy and safety of once-daily intravenous (IV) eravacycline compared to ertapenem for the treatment of patients with complicated urinary tract infections (cUTI) did not achieve statistical non-inferiority of eravacycline to ertapenem. The study failed to meet the co-primary efficacy endpoints of responder rate (a combination of clinical cure and microbiological success) in the microbiological intent-to-treat (micro-ITT) population at the end-of-IV (EOI) treatment visit and at the test-of-cure (TOC) visit, which were evaluated using a 10% non-inferiority margin. Eravacycline was well tolerated in IGNITE3, with a safety profile consistent with prior studies.

“We are surprised and obviously very disappointed that the IGNITE3 trial did not achieve its co-primary endpoints and are fully analyzing the data to understand this outcome,” said Guy Macdonald, President and CEO of Tetraphase. “Independent of this outcome, we continue to move forward with our registration strategy for eravacycline in complicated intra-abdominal infections (cIAI). We currently have an NDA under review with the FDA as well as an MAA under review by the EMA in Europe, which are based on the positive outcomes demonstrating high cure rates and favorable tolerability in the IGNITE1 and IGNITE4 phase 3 clinical trials of IV eravacycline in cIAI. We are actively preparing for the commercialization of eravacycline as a treatment in cIAI in both the U.S and in Europe, assuming regulatory approvals.”

Mr. Macdonald continued: “There is a clear unmet need for patients with serious infections, particularly those caused by difficult-to-treat Gram-negative bacteria, and we continue to believe that eravacycline can benefit those patients and we are excited to be getting closer to delivering that potential to patients in need."

The phase 3 IGNITE3 clinical trial enrolled 1,205 patients who were randomized 1:1 to receive IV eravacycline (1.5mg/kg every 24 hours) or ertapenem (1g every 24 hours) for a minimum of 5 days, and then were eligible for transition to an appropriate approved oral agent. The co-primary endpoints of responder rate (a combination of clinical cure and microbiological success) in the microbiological intent-to-treat (micro-ITT) population at the EOI visit and at the TOC visit (Day 5-10 post therapy) were evaluated using a 10% non-inferiority margin. Responder rates in the micro-ITT population at the EOI visit were 84.8% and 94.8% for eravacycline (n=363/428) and ertapenem (n=382/403), respectively (-10% CI: -14.1%, -6.0%). Responder rates at the TOC visit were 68.5% and 74.9% for eravacycline (n=293/428) and ertapenem (n=302/403), respectively (-6.5% CI: -12.6%, -0.3%).

Conference Call Information
Tetraphase will host a conference call today at 4:30 pm Eastern Time to discuss the top-line data from the phase 3 IGNITE3 clinical trial. The call can be accessed by dialing (844) 831-4023 (U.S. and Canada) or (731) 256-5215 (international) and entering Conference ID 7069413. To access the live audio webcast, or the subsequent archived recording, visit the "Investors Relations — Events & Presentations" section of the Tetraphase website at www.tphase.com. The webcast will be recorded and available for replay on the Tetraphase website for 30 days following the call.

About IGNITE3
IGNITE3 was a phase 3 randomized, multi-center, double-blind, 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 cUTI. IGNITE3 enrolled approximately 1,200 patients who were randomized 1:1 to receive eravacycline or ertapenem for a minimum of 5 days, and then were eligible for transition to an appropriate approved oral agent. The co-primary endpoints of responder rate (a combination of clinical cure and microbiological success) 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) were evaluated using a 10% non-inferiority margin.

About Eravacycline
Eravacycline is a novel, fully-synthetic fluorocycline 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 & Prevention (CDC). In clinical trials, eravacycline has demonstrated potent activity against multidrug-resistant (MDR) pathogens, including carbapenem-resistant enterobacteriaceae (CRE), Acinetobacter baumannii, and colistin-resistant bacteria carrying the mcr-1 gene.

Eravacycline was investigated in the Company's IGNITE (Investigating Gram-negative Infections Treated with Eravacycline) phase 3 programs. To date, eravacycline has been administered to over 2,700 patients and in two completed phase 3 trials in cIAI, and two completed phase 3 trials in cUTI. In IGNITE1, a pivotal phase 3 trial in patients with cIAI, 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. The IGNITE1 data is serving as the basis of the Marketing Authorization Application (MAA) for IV eravacycline for the treatment of patients with cIAI now under review by the European Medicines Agency (EMA). In IGNITE4, a second phase 3 clinical trial in patients with cIAI, twice-daily IV eravacycline met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to meropenem, was well tolerated, and achieved high cure rates. The Company has used the results from IGNITE1 and IGNITE4 to support a New Drug Application (NDA) submission for IV eravacycline in cIAI. In IGNITE3, once-daily IV eravacycline did not achieve co-primary endpoints and did not achieve statistical non-inferiority of clinical response compared to ertapenem. In IGNITE2, the primary endpoint was also not met.

About Tetraphase Pharmaceuticals, Inc.
Tetraphase is a 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 has completed phase 3 clinical trials and is under review for potential approval in complicated intra-abdominal infections by the U.S. Food and Drug Administration (FDA) and the EMA, and TP-271 and TP-6076, which are in phase 1 clinical trials. Eravacycline is an investigational product only and has not been approved for commercialization. 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 the results of the Company's development efforts will warrant regulatory submission and whether any such submissions will receive 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 1, 2017. In addition, the forward-looking statements included in this press release represent our views as of February 13, 2018. 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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