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Tetraphase Pharmaceuticals Completes Enrollment of IGNITE3 Phase 3 Clinical Trial of Eravacycline in Complicated Urinary Tract Infections

- Top-line Data Expected in 1Q 2018 -

- IGNITE3 Results to Support U.S. sNDA Filing for IV Eravacycline in cUTI -

WATERTOWN, Mass., Sept. 11, 2017 (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 completion of enrollment in IGNITE3, its ongoing phase 3 clinical trial evaluating the efficacy and safety of once-daily intravenous (IV) eravacycline compared to ertapenem in complicated urinary tract infections (cUTI). The Company expects to report top-line data from this trial in the first quarter of 2018.

"We have now completed enrollment of approximately 1,200 patients in IGNITE3, well ahead of schedule, and we expect top-line data from IGNITE3 to be available during the first quarter of 2018," said Guy Macdonald, President and CEO of Tetraphase. "In parallel, we are working to prepare a New Drug Application (NDA) for twice-daily IV eravacycline in complicated intra-abdominal infections, which will be comprised of data from the successfully completed phase 3 IGNITE1 and IGNITE4 clinical trials. Assuming a positive outcome from IGNITE3 and approval of IV eravacycline for the treatment of cIAI, we plan to file a supplemental NDA (sNDA) for IV eravacycline as a new treatment for patients with cUTI."

Mr. Macdonald added, "With high rates of quinolone resistance in hospitals in the U.S. and around the world, we believe a once-daily IV therapy for cUTI could be an important new treatment option for patients who are eligible for completing their course of antibiotics in an outpatient setting."

About IGNITE3
IGNITE3 is 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 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) will be 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 (CDC). 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 is in 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 administered to over 1,500 patients and in two completed phase 3 trials in cIAI. 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. The IGNITE1 data is serving as the basis of the Marketing Authorization Application for IV eravacycline for the treatment of patients with cIAI now under review by the European Medicines Agency. 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 plans to use the results from IGNITE1 and IGNITE4 to support an NDA submission for IV eravacycline in cIAI in the first quarter of 2018. Tetraphase is also currently conducting IGNITE3, an additional phase 3 trial evaluating once-daily IV eravacycline in patients with cUTI and, assuming a positive outcome from IGNITE3 and approval of IV eravacycline for the treatment of cIAI, the Company plans to use the results from IGNITE3 to support a supplemental NDA 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 a phase 3 clinical program, 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 previous clinical trials will be indicative of results obtained in future clinical trials; whether any clinical candidate will advance through the clinical trial process on a timely basis or at all; 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 August 2, 2017. In addition, the forward-looking statements included in this press release represent our views as of September 11, 2017. 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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