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Tetraphase Pharmaceuticals Doses First Patient in IGNITE3 Phase 3 Clinical Trial of Once-daily IV Eravacycline in cUTI

WATERTOWN, Mass., Jan. 17, 2017 (GLOBE NEWSWIRE) -- Tetraphase Pharmaceuticals, Inc. (NASDAQ:TTPH) today announced dosing of the first patient in IGNITE3, the Company's phase 3 clinical trial evaluating the efficacy and safety of once-daily intravenous (IV) eravacycline compared to ertapenem in complicated urinary tract infections (cUTI). Eravacycline is a novel antibiotic candidate with potent activity against multidrug-resistant (MDR) pathogens, including carbapenem-resistant *Enterobacteriaceae* (CRE), *Acinetobacter baumannii*, and colistin-resistant bacteria carrying the *mcr-1* gene, that is being developed for the treatment of serious and life-threatening bacterial infections.

"We are pleased to have initiated patient enrollment for IGNITE3 in cUTI, the second indication for which eravacycline is being evaluated," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "Assuming a positive outcome from this study, these data are expected to support a supplemental New Drug Application (sNDA) submission for IV eravacycline in cUTI. We remain on track to report top-line results from the ongoing IGNITE4 study in complicated intra-abdominal infections during the fourth quarter of 2017, followed by an NDA submission for IV eravacycline in cIAI."

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 is expected to enroll approximately 1,000 patients who will be randomized 1:1 to receive eravacycline or ertapenem for a minimum of 5 days, and will then be eligible for transition to an 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 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 administered to over 1,300 patients and has been evaluated 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. The company plans to use the data from the IGNITE1 clinical trial to support a Marketing Authorization Application submission to the European Medicines Agency in the second half of 2017 for IV eravacycline for the treatment of patients with cIAI. 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. 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, 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 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 previous 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 January 17, 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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