Tetraphase Pharmaceuticals Receives Positive CHMP Opinion for Xerava™ (eravacycline) as a Treatment for Complicated Intra-Abdominal Infections

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WATERTOWN, Mass., July 27, 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 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending Xerava (eravacycline) for approval as a treatment for adult patients with complicated intra-abdominal infections (cIAI). The CHMP's opinion will be reviewed by the European Commission (EC) which is expected to make a final decision within three months. If approved by the EC, marketing authorization for Xerava will be granted in all 28 countries of the European Union, Norway, Iceland and Liechtenstein.

"We are highly encouraged by the CHMP's opinion recommending Xerava for the treatment of cIAI, as it marks an exciting milestone in reaching our goal of bringing this antibiotic to patients in Europe," said Guy Macdonald, President and Chief Executive Officer of Tetraphase Pharmaceuticals. "This is a particularly promising time for Tetraphase and Xerava. In addition to the positive CHMP opinion, we have a New Drug Application (NDA) under review by the U.S. Food and Drug Administration (FDA) with an upcoming Prescription Drug User Fee Act (PDUFA) date in August, and just last month Everest Medicines submitted an Investigational New Drug application to China'sFood and Drug Administration to conduct a phase 3 clinical trial of eravacycline in cIAI in China."

Mr. Macdonald added, "We believe Xerava is well-positioned to be an empiric antibiotic treatment for cIAI. It also provides physicians an alternative to carbapenems and beta-lactams with beta-lactamase inhibitors. In institutions where Gram-negative resistance is a concern, we feel Xerava offers a clear advantage because it covers many MDR pathogens, which some carbapenems and beta-lactams with beta-lactamase inhibitors do not. We look forward to the continued collaboration with the EMA to complete the regulatory process in Europe."

The CHMP opinion is based on a comprehensive data package from IGNITE1 and IGNITE4, which were part of the Company's phase 3 **I**nvestigating **G**ram-**n**egative **I**nfections **T**reated with **E**ravacycline (IGNITE) program. In IGNITE1, twice-daily intravenous (IV) Xerava met the primary endpoint, demonstrating non-inferiority in clinical cure versus IV ertapenem in 536 patients using a 10% non-inferiority margin. In IGNITE4, a second phase 3 clinical trial in patients with cIAI, twice-daily IV Xerava met the primary endpoint, demonstrating non-inferiority in clinical cure versus IV meropenem in 500 patients using a 12.5% non-inferiority margin. In both IGNITE1 and IGNITE4, Xerava was well-tolerated and achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates. The Company is also using the results from IGNITE1 and IGNITE4 to support a NDA for Xerava in cIAI with the FDA.

About Xerava
Xerava is a novel, fully-synthetic fluorocycline antibiotic being developed for the treatment of cIAI and other serious infections, including those caused by MDR pathogens that have been highlighted as urgent public health threats by both the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC). Xerava has demonstrated potent activity against MDR pathogens including Enterobacteriaceae and *Acinetobacter baumannii* and colistin-resistant bacteria carrying the *mcr-1* gene. In addition to being under review by the EMA, Xerava is currently under review with the FDA with a PDUFA date of August 28, 2018.

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 MDR bacteria highlighted as urgent public health threats by the WHO and CDC. The Company has created more than 3,000 novel tetracycline compounds using its proprietary technology platform. Tetraphase's pipeline includes three antibiotic clinical candidates: Xerava, TP-271 and TP-6076. Xerava has completed phase 3 clinical testing and is under review for potential approval in cIAI by the FDA and has received a positive opinion from the CHMP. TP-271 and TP-6076 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 the Company's regulatory submission will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if any clinical candidate, including Xerava (eravacycline), 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 for the period ended March 31, 2018, filed with the Securities and Exchange Commission on May 3, 2018. In addition, the forward-looking statements included in this press release represent our views as of July 27, 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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