

# Tetraphase Pharmaceuticals Announces Everest Medicines' Submission of an Investigational New Drug Application for Eravacycline in Complicated Intra-Abdominal Infection to the China Food and Drug Administration

June 4, 2018

WATERTOWN, Mass., June 04, 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 Everest Medicines Limited ("Everest"), a C-Bridge Capital-backed biopharmaceutical company based in China which has the exclusive license to develop and commercialize eravacycline in China, Taiwan, Hong Kong, Macau, South Korea and Singapore (the "Territories"), has submitted an Investigational New Drug (IND) application to China's Food and Drug Administration (CFDA) for a phase 3 clinical trial of eravacycline in complicated intra-abdominal infections (cIAI).

"Everest's IND submission to the CFDA ahead of schedule marks an important milestone in our strategy to make eravacycline available as a new antibiotic treatment option for serious, MDR infections," said Guy Macdonald, President and CEO of Tetraphase. "We are delighted with Everest's rapid progress, which speaks to its development expertise and our highly collaborative working relationship, and we look forward to providing future updates as the process continues."

As a result of the IND submission, Tetraphase will receive a milestone payment of \$2.5 million. Under the terms of the agreement, Tetraphase may receive future clinical and regulatory milestones of up to \$14 million as well as sales milestones of up to \$20 million. Tetraphase is also eligible to receive double-digit tiered royalties on net sales of eravacycline in the Territories. Everest is solely responsible for the development and commercialization of eravacycline in the Territories.

Mr. Macdonald added, "This remains an exciting time for Tetraphase and for the potential of eravacycline in cIAI, with a New Drug Application under review by the U.S. Food and Drug Administration and a Marketing Authorization Application under review by the European Medicines Agency. Now, with Everest's IND submitted, we are one step closer to bringing eravacycline to patients in need on a global level."

## About Eravacycline

Eravacycline 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 and the U.S. Centers for Disease Control & Prevention (CDC). In clinical trials, eravacycline has demonstrated potent activity against MDR pathogens, including carbapenem-resistant Enterobacteriaceae, *Acinetobacter baumannii* and colistin-resistant bacteria carrying the mcr-1 gene.

Eravacycline was investigated for the treatment of cIAI as part of the Company's IGNITE (Investigating Gram-negative Infections Treated with Eravacycline) phase 3 programs. 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 NDA submission for IV eravacycline in cIAI which is under review by the FDA with a Prescription Drug User Fee Act (PDUFA) date of August 28, 2018. To date, in clinical trials, eravacycline has been administered to over 2,700 patients. Eravacycline has not been approved for commercial use.

## 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 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: eravacycline, which has completed phase 3 clinical trials and is under review for potential approval in cIAI by the FDA and the EMA, and TP-271 and TP-6076, which are in phase 1 clinical trials. Please visit [www.tphase.com](http://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 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 June 4, 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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