

Tetraphase Pharmaceuticals Announces FDA Acceptance for Filing of its NDA Submission for Eravacycline for the Treatment of Complicated Intra-Abdominal Infections (cIAI)

February 27, 2018

PDUFA Date Set for August 28, 2018

WATERTOWN, Mass., Feb. 27, 2018 (GLOBE NEWSWIRE) -- [Tetraphase Pharmaceuticals, Inc.](#) (NASDAQ:TPPH), a biopharmaceutical company focused on developing and commercializing novel antibiotics to treat life-threatening multidrug-resistant (MDR) infections, today announced that it has received notification from the U.S. Food and Drug Administration (FDA) that the FDA has completed its initial 60-day review of the New Drug Application (NDA) for eravacycline for the treatment of complicated intra-abdominal infections (cIAI), and determined that the application is sufficiently complete to permit a substantive review. The PDUFA (Prescription Drug User Fee Act) goal date for the completion of the FDA's review of the eravacycline NDA is set for August 28, 2018. This date reflects a priority 6-month review period.

"The FDA's acceptance for review of our NDA submission for IV eravacycline in cIAI marks an important step in our goal to bring this important new treatment option to patients in need," said Guy Macdonald, President and CEO of Tetraphase. "We believe that eravacycline has the potential to play a key role in the treatment of serious intra-abdominal infections, particularly Gram-negative infections, and we look forward to providing an update on a regulatory decision in August as we continue to prepare for a commercial launch."

The NDA submission includes data from the IGNITE1 and IGNITE 4 phase 3 clinical trials, in which twice-daily IV eravacycline was well tolerated and achieved high clinical cure rates in patients with cIAI. Both studies demonstrated statistical non-inferiority of eravacycline to two widely used comparators – ertapenem in IGNITE1 and meropenem in IGNITE4 – for the primary efficacy endpoint of clinical response at the test-of-cure (TOC) visit.

About Eravacycline

Eravacycline is a novel, fully-synthetic fluorocycline antibiotic being developed for the treatment of complicated intra-abdominal infections (cIAI) and other 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 MDR pathogens, including carbapenem-resistant enterobacteriaceae (CRE), *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 New Drug Application (NDA) submission for IV eravacycline in cIAI. To date, eravacycline has been administered to over 2,700 patients.

About Complicated Intra-abdominal Infections (cIAI)

Intra-abdominal infection (IAI) is a common problem in clinical practice and comprises a wide variety of disease processes. IAI is classified as uncomplicated or complicated based on the extent of the infection. Complicated intra-abdominal infection extends beyond the source organ into the peritoneal space (the space between the two membranes that separate the organs in the abdominal cavity from the abdominal wall) as a result of perforation or other damage to the gastrointestinal tract. cIAI diagnoses include intra-abdominal abscess, stomach or intestinal perforation, peritonitis, appendicitis, cholecystitis, or diverticulitis. Different bacterial pathogens are responsible for cIAI, including Gram-negative aerobic bacteria, Gram-positive bacteria, and anaerobic bacteria, and there are also mixed infections. IAI is an important cause of morbidity and mortality and is the second most common cause of infectious mortality in the intensive care unit. Early detection, containment and appropriate antimicrobial treatment are essential to the successful treatment of IAI. This is even more critical with increasing rates of infections caused by drug-resistant bacteria, which limit the effectiveness of currently available antibiotics.

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. 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 Company's regulatory submissions will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if 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, 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 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.

Investor Contact:

Argot Partners
Maeve Conneighton
206-899-4940
maeve@argotpartners.com

Media Contact:

Sam Brown Inc.
Mike Beyer

312-961-2502

Mikebeyer@sambrown.com

Primary Logo

Source: Tetrphase Pharmaceuticals, Inc.