Tetraphase Pharmaceuticals Announces Submission of New Drug Application to FDA for Eravacycline for the Treatment of Complicated Intra-Abdominal Infections (cIAI)

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Submission Supported by Positive Data from IGNITE1 and IGNITE4 Clinical Trials

WATERTOWN, Mass., Jan. 02, 2018 (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 that it has submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for intravenous (IV) eravacycline for the treatment of complicated intra-abdominal infections (cIAI).

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.

“The submission of the NDA filing for IV eravacycline, supported by positive data from two pivotal trials investigating the drug for the treatment of cIAI, is a critical milestone for Tetraphase,” 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 hospital infections, particularly Gram-negative infections. We are now one step closer to realizing the goal of bringing this medicine to the market."

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 & Prevention (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 phase 3 clinical development for the treatment of complicated urinary tract infections (cUTI).

Eravacycline is currently being investigated in the Company's IGNITE (Investigating Gram-negative Infections Treated with Eravacycline) phase 3 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 MAA for IV eravacycline for the treatment of patients with cIAI now under review by the 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 an NDA submission for IV eravacycline in cIAI. Tetraphase has completed enrollment of 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 formulation of eravacycline. A phase 2 trial of the current formulation is expected to begin in the first half of 2018 and a phase 1 clinical program is ongoing which is designed to evaluate and optimize the oral formulation.

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 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 has completed enrollment 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 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 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 November 1, 2017. In addition, the forward-looking statements included in this press release represent our views as of January 2, 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.

Investor Contacts:
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: Tetraphase Pharmaceuticals, Inc.