Tetraphase Pharmaceuticals Announces FDA Approval of XERAVA™ (Eravacycline) for Complicated Intra-Abdominal Infections (cIAI)

August 27, 2018

– XERAVA™Achieved High Clinical Cure Rates in Clinical Trials in Patients with cIAI –

– Broad Product Label for Treatment of cIAI –

– Commercial Launch Expected in the Fourth Quarter of 2018 –

– Conference Call Scheduled for Today at 4:30 p.m. ET –

WATERTOWN, Mass., Aug. 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 U.S. Food and Drug Administration (FDA) has granted approval of XERAVA™ (eravacycline) for the treatment of complicated intra-abdominal infections (cIAI). In clinical trials, XERAVA was well-tolerated and achieved high clinical cure rates in patients with cIAI, demonstrating statistical non-inferiority to two widely used comparators – ertapenem and meropenem.

XERAVA is indicated for the treatment of complicated intra-abdominal infections in patients 18 years of age and older. To reduce the development of drug-resistant bacteria and maintain the effectiveness of XERAVA and other antibacterial drugs, XERAVA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

“The approval of XERAVA is an extraordinary achievement, one for which we thank the patients who have participated in our clinical studies, study investigators and physicians as well as our dedicated employees,” said Guy Macdonald, President and Chief Executive Officer of Tetraphase. “We are thrilled to have received FDA approval, and a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in Europe all within the same quarter. Each milestone is a significant accomplishment on its own and achieving both underscores the potential for Tetraphase and the medical need for XERAVA.”

Mr. Macdonald added, “We will now turn our efforts towards delivering XERAVA to patients suffering from cIAI in the United States, an important goal we expect to begin executing on in the fourth quarter of this year. We look forward to a successful launch and commercialization moving forward.”

“Complicated intra-abdominal infections are the second-most prevalent infection site in intensive care units (ICUs), as well as the second leading cause of infection-related mortality in ICUs,” said Philip S. Barie, MD, MBA, Professor of Surgery and Professor of Public Health in Medicine at Weill Cornell Medicine, and an attending surgeon at New York-Presbyterian/Weill Cornell Medical Center in New York City. “With the growing crisis of antibiotic resistance, treatment options for these polymicrobial infections are limited following surgery or percutaneous drainage, and the causative pathogens may be multi-drug resistant. Current empiric treatments for cIAI have limitations, and there is a need for new and novel treatments. Eravacycline has a broad spectrum of antibacterial activity and a clinical profile that addresses this unmet medical need.”

Dr. Barie added, “Eravacycline also has a favorable safety profile as observed in clinical trials, and no dose adjustment is required when given to patients with renal impairment, which is advantageous for seriously ill patients who may have impaired kidney function. Additionally, the drug may be given safely to patients who are allergic to penicillin. This new and novel treatment may be of great benefit to patients with complicated intra-abdominal infections.”

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 infections (cIAI) extend 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. 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.

“Today’s FDA approval of XERAVA provides a new weapon in the battle against antibiotic resistance and addresses an unmet medical need for patients suffering from multi-drug resistant infections and other serious infections” said Rick A. Bright Ph.D., Director of the Biomedical Advanced Research and Development Authority (BARDA). “We are pleased to have provided support to Tetraphase since 2012, through its collaboration with CUBRC, to develop this new antibiotic treatment. The drug’s approval underscores the value of public-private partnerships in addressing global health threats and the challenge of antibiotic resistance.”

Conference Call Information
Tetraphase will host a conference call today at 4:30 p.m. Eastern Time to discuss the FDA approval. The call can be accessed by dialing (844) 831-4023 (U.S. and Canada) or (731) 256-5215 (international) and entering conference ID number 2585575. To access the live audio webcast, or the subsequent archived recording, visit the "Investors Relations — Events & Presentations" section of the Tetraphase website at www.tphase.com.

A replay of the conference call will be available from 7:30 p.m. ET on Monday, August 27, 2018, through 7:30 p.m. ET on Wednesday, September 25, 2018, and may be accessed by visiting Tetraphase’s website or by dialing 1-855-859-2056 (U.S. and Canada) and 1-404-537-3406 for (international) callers. The conference ID number is 2585575.

Important Safety Information

XERAVA is a tetracycline class antibacterial indicated for the treatment of complicated intra-abdominal infections in patients 18 years of age and older.

XERAVA is not indicated for the treatment of complicated urinary tract infections.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of XERAVA and other antibacterial drugs, XERAVA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

XERAVA is contraindicated for use in patients with known hypersensitivity to eravacycline or to tetracycline-class antibacterial drugs. Life-threatening hypersensitivity (anaphylactic) reactions have been reported with XERAVA.

The use of XERAVA during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

The use of XERAVA during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis.

The most common adverse reactions observed in clinical trials (incidence ≥ 3%) were infusion site reactions, nausea, and vomiting.

XERAVA is structurally similar to tetracycline-class antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests, have been reported for other tetracycline-class antibacterial drugs, and may occur with XERAVA. Discontinue XERAVA if any of these adverse reactions are suspected.

To report SUSPECTED ADVERSE REACTIONS, contact Tetraphase Pharmaceuticals Inc., at 1-833- 7-XERAVA (1-833-793-7282) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Please see full prescribing information for XERAVA.

About XERAVA ™
XERAVA (eravacycline for injection) is a novel, fully-synthetic fluorocycline, FDA-approved antibiotic for the treatment of cIAI. XERAVA has demonstrated potent activity against MDR pathogens.

XERAVA was investigated for the treatment of cIAI as part of the Company's IGNITE (**I**nvestigating **G**ram-**N**egative **I**nfections **T**reated with **E**ravacycline) phase 3 programs. In the first pivotal phase 3 trial in patients with cIAI, twice-daily intravenous (IV) eravacycline met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to ertapenem and was well-tolerated. In the 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 and was well-tolerated. In both trials, XERAVA achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates.

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 lead product, XERAVA™ (eravacycline) is FDA-approved for the treatment of complicated intra-abdominal infections (cIAI), has received a positive opinion from the CHMP for cIAI, and is under consideration for potential marketing approval by the European Commission for cIAI. The company's pipeline also includes 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 eravacycline will be successfully distributed and marketed and other regulatory and commercial risk factors discussed in the "Risk Factors" section of our quarterly report on Form 10-Q for the period ended June 30, 2018, filed with the Securities and Exchange Commission on August 2, 2018. In addition, the forward-looking statements included in this press release represent our views as of August 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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