Tetraphase Pharmaceuticals Announces Adoption of Commission Decision Granting Marketing Authorisation Approval in the European Union for XERAVA™ (eravacycline) for the Treatment of Complicated Intra-Abdominal Infections

September 20, 2018

– Broad Product Label for Treatment of Complicated Intra-Abdominal Infections –

– PhasedCommercial Launch Expected in the First Half of 2019 –

WATERTOWN, Mass., Sept. 20, 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 European Commission (EC) has adopted the Decision granting marketing authorisation for XERAVA (eravacycline) for injection for the treatment of complicated intra-abdominal infections (cIAI) in adults in the European Union. 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.

"The European approval of XERAVA, right after our recently announced FDA approval, marks our second significant regulatory approval within one month and reflects our commitment to bringing this novel antibiotic to patients on a global level," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "We are excited about the approval of XERAVA in Europe, and we remain on track to launch in Europe via a phased introduction, beginning with Germany and the UK, in early 2019."

Mr. Macdonald added, "Once again, we are grateful to the patients who have participated in our clinical studies, study investigators, physicians and our dedicated employees for bringing us to this important milestone for the Company. With the growing crisis of antibiotic resistance and the limitations of current empiric treatments for cIAI, the medical community is desperately in need of new antibiotics. Given its broad spectrum of antibacterial activity and clinical and safety profile, we believe XERAVA has the potential to address this need, and we look forward to a successful launch."

The European Commission approval follows the positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) and allows Tetraphase to market XERAVA in all countries in the European Union as well as Iceland, Liechtenstein and Norway. The decision was based on a comprehensive data package which included data from the Company's phase 3 clinical trials investigating XERAVA in patients with cIAI compared to ertapenem and meropenem. In the first trial, twice-daily intravenous (IV) XERAVA met the primary endpoint, demonstrating non-inferiority in clinical cure versus IV ertapenem. In the second trial, twice-daily IV XERAVA met the primary endpoint, demonstrating non-inferiority in clinical cure versus IV meropenem. In both trials, XERAVA was well-tolerated and achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates.

"The approval of XERAVA in Europe represents a significant advancement for patients impacted by serious and life-threatening infections caused by multidrug-resistant pathogens," said Matteo Bassetti, M.D., Ph.D., Head of the Infectious Diseases Division of the Santa Maria Misericordia University Hospital, Udine, Italy and Associate Professor of Infectious Diseases of the University of Udine. "XERAVA's broad spectrum of coverage against Gram-negative, Gram-positive and anaerobic bacteria allow it to fill an unmet need for patients with complicated intra-abdominal infections, and it is also well-suited as a first-line empiric treatment for appropriate patients. XERAVA offers an alternative to beta-lactams, including carbapenems which are experiencing more resistance, making this important new antibiotic a welcome option for physicians."

About 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 for 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.

Indications and Usage
XERAVA is indicated for the treatment of complicated intra-abdominal infections (cIAI) caused by susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii, Enterobacter cloacae, Klebsiella oxytoca, Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus, Streptococcus anginosus* group*, Clostridium perfringens, Bacteroides species, and Parabacteroides distasonis* in patients 18 years or older.

Limitations of Use
XERAVA is not indicated for the treatment of complicated urinary tract infections (cUTI).

Usage
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. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Important Safety Information
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 (7.7%), nausea (6.5%), and vomiting (3.7%).

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.

About XERAVA
XERAVA (eravacycline) for injection is a tetracycline class antibacterial indicated for the treatment of complicated intra-abdominal infections (cIAI) in patients 18 years of age and older. It is approved for use in the U.S. and Europe. 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 multidrug-resistant bacteria highlighted as urgent public health threats by the World Health Organization and the Centers for Disease Control and Prevention. The Company has created more than 3,000 novel tetracycline compounds using its proprietary technology platform. Tetraphase's lead product XERAVA is approved for the treatment of complicated intra-abdominal infections (cIAI) by the U.S. Food and Drug Administration and the European Commission. 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 September 20 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.

Media and Investor Contact:
Tetraphase Pharmaceuticals
Jennifer Viera
617-600-7040
jviera@tphase.com

TETRAPHASE PHARMACEUTICALS

Source: Tetraphase Pharmaceuticals, Inc.