



## Tetraphase Pharmaceuticals Announces Commercial Launch of XERAVA™ in the United States

October 11, 2018

*FDA-Approved for the Treatment of Complicated Intra-Abdominal Infections*

*Provides Broad Spectrum of Coverage Against Gram-negative, Gram-positive, and Anaerobic Bacteria for a Range of Patients with Empiric and Confirmed Infections*

WATERTOWN, Mass., Oct. 11, 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 the U.S. commercial launch of XERAVA™ (eravacycline) for the treatment of complicated intra-abdominal infections (cIAI). The wholesale acquisition cost (WAC) of XERAVA will be \$175 per day of therapy to support the Company's strategy of having XERAVA used for the empiric treatment of cIAI.

"The launch of XERAVA marks an important milestone for Tetraphase and for physicians with patients in need of a new broad-spectrum antibiotic for serious, often life-threatening, multidrug-resistant infections," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "This important achievement marks the culmination of many years of dedication and follows the regulatory approvals of XERAVA both by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency.

"We are well-prepared for the commercial success of XERAVA with a strong and experienced sales team who are fully-trained and deployed to make the treatment widely available to patients in need," said Larry Edwards, Chief Operating Officer of Tetraphase. "With a WAC price of \$175 per treatment day, XERAVA is well-suited for empiric use and is now available to hospitals to treat a range of appropriate patients with empiric and confirmed infections. The salesforce will be focusing on healthcare institutions responsible for treating the highest concentrations of Gram-negative infections, covering approximately 90% of the Gram-negative marketplace."

### About Complicated Intra-Abdominal Infections

Intra-abdominal infection (IAI) 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 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.

### 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. XERAVA was investigated for the treatment of cIAI as part of the Company's IGNITE (Investigating Gram-Negative Infections Treated with Eravacycline) Phase 3 program. In the first pivotal Phase 3 trial in patients with cIAI, twice-daily intravenous (IV) XERAVA 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 XERAVA 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.

### 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 eight 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 eight 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  $\geq$  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](http://www.fda.gov/medwatch)**

Please see full prescribing information for XERAVA at [www.XERAVA.com](http://www.XERAVA.com).

#### **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 by the U.S. Food and Drug Administration and the European Medicines Agency. The Company's pipeline also includes 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 XERAVA 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 October 11, 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 and Media Contacts:**

Tetraphase Pharmaceuticals  
Jennifer Viera  
617-600-7040  
[jviera@tphase.com](mailto:jviera@tphase.com)



Source: Tetraphase Pharmaceuticals, Inc.