Tetraphase Pharmaceuticals Announces Presentation of Positive Data from Phase 3 Trials of XERAVA™ (eravacycline) and Multiple-Ascending Dose Trial of TP-6076 at IDWeek 2018

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XERAVA Demonstrated Efficacy in Treating Secondary Bacteremia in Patients with Complicated Intra-Abdominal Infections in Post-Hoc Analysis of Phase 3 Clinical Trials

TP-6076 Demonstrated Favorable Pharmacokinetic and Safety Profile in Phase 1 Trial, Supporting Advancement into a Bronchopulmonary Disposition Study

WATERTOWN, Mass., Oct. 08, 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, announced data from a pooled analysis of two Phase 3 studies of XERAVA in complicated intra-abdominal infection (cIAI) and a Phase 1 multiple-ascending dose study for its pipeline candidate TP-6076. These data were presented at the Infectious Disease Society of America's (IDSA) Infectious Disease Week (IDWeek) 2018, held October 3-7 in San Francisco.

"The data presented at IDWeek demonstrate high clinical cure rates and microbiological eradication with XERAVA among patients with cIAI and concurrent bacteremia," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "These data confirm the efficacy of XERAVA in a subgroup of cIAI patients who may be at higher risk for poor outcomes, and this new analysis comes at an exciting time as we make final preparations for the commercial launch of XERAVA in the coming weeks."

Mr. Macdonald added, "We are also encouraged by the positive safety, tolerability and pharmacokinetic data from the multiple-ascending dose Phase 1 study evaluating a seven-day dosing regimen for intravenous (IV) TP-6076. We plan to advance TP-6076 to a bronchopulmonary disposition study beginning in the first quarter of 2019 to confirm appropriate therapeutic levels of TP-6076 in the lungs to treat infections caused by *Acinetobacter baumannii* and other MDR pathogens. In previously completed *in vitro* testing, TP-6076 MIC_{90} values were as much as 64-fold lower than those for tigecycline against MDR Gram-negative pathogens, including *Acinetobacter baumannii*, suggesting that TP-6076 could be a potent treatment for these difficult-to-treat bacteria. We are enthusiastic about the potential for TP-6076 and the future of this program."

Efficacy of Eravacycline in Secondary Bacteremia: A Post-Hoc Analysis of Two Phase 3 Studies of Complicated Intra-Abdominal Infections

XERAVA was evaluated for the treatment of cIAI in two Phase 3 clinical trials. The objective of this post-hoc analysis was to evaluate microbiological response at the test of cure (TOC) visit in patients with baseline bacteremia who received XERAVA versus comparators ertapenem and meropenem.

Pooled data from the Phase 3 studies were analyzed. All patients enrolled were randomized (1:1) to receive XERAVA 1 mg/kg IV every 12 hours or ertapenem 1 g IV every 24 hours, (IGNITE1 study) or meropenem 1g IV every 8 hours, (IGNITE4 study) for 4-14 days. Blood and intra-abdominal samples were collected from all patients. Clinical outcome at the TOC visit (28 days after randomization) in the microbiological-intention to treat population (micro-ITT) was the primary efficacy endpoint.

Among the 415 patients treated with XERAVA and 431 patients treated with comparators, 39 and 40 patients, respectively, had concurrent bacteremia. For patients with concurrent bacteremia caused by Gram-positive bacteria or anaerobes, the microbiological eradication was 100% for those treated with XERAVA as well as for those treated with comparators. Patients with bacteremia due to Gram-negative pathogens, including Escherichia coli, achieved 93% microbiological eradication when treated with XERAVA or a comparator.

Safety, Tolerability and Pharmacokinetics of Multiple Doses of TP-6076, a Novel, Fully Synthetic Tetracycline

This poster presentation highlighted data from a Phase 1 randomized, placebo-controlled, double-blind, multiple-ascending-dose study evaluating the safety, tolerability and pharmacokinetics of TP-6076 conducted at a single center in 40 healthy volunteers. Cohorts of eight subjects each were randomized 6:2 to receive daily doses ranging from 6.0 mg to 40 mg, or placebo.

In this study, TP-6076 was generally well tolerated, and there were no serious or severe adverse events. There were no clinically significant safety findings in any laboratory assessments, vital signs, electrocardiographs, or physical examinations. The most frequently reported adverse events were gastrointestinal events, including nausea and vomiting, and localized infusion-site reactions.

TP-6076 is a novel, synthetic, fluorocycline antibiotic candidate being developed for the treatment of serious and life-threatening bacterial infections, including those caused by pathogens otherwise resistant to current treatment options. It has demonstrated potent *in vitro* activity against multidrug-resistant bacteria including carbapenem-resistant *Enterobacteriaceae* and carbapenem-resistant *Acinetobacter baumannii*.

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 (**I**nvestigating **G**ram-**N**egative **I**nfections **T**reated with **E**ravacycline) 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 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

Please see full prescribing information for XERAVA at 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 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; whether results obtained in previous clinical trials will be indicative of results obtained in future clinical trials; whether any clinical candidate will advance through the clinical trial process on a timely basis or at all 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 8, 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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