

June 5, 2017

Tetraphase Pharmaceuticals Announces Positive Phase 1 Single-Ascending Dose Data for Antibiotic Pipeline Candidates

Both TP-6076 and TP-271 Demonstrated Favorable Pharmacokinetic and Safety Profiles, Supporting Advancement into Multiple-Ascending Dose Studies

WATERTOWN, Mass., June 05, 2017 (GLOBE NEWSWIRE) -- [Tetraphase Pharmaceuticals, Inc.](http://www.tetraphase.com) (NASDAQ:TTPH), a clinical stage biopharmaceutical company developing novel antibiotics to treat life-threatening multidrug-resistant (MDR) infections, today announced positive data from phase 1 single-ascending dose studies for its two pipeline programs, TP-6076 and TP-271. These data were presented at the American Society for Microbiology (ASM) Microbe 2017 Annual Meeting, held June 1-5, 2017 in New Orleans, LA.

"We are pleased with the positive safety, tolerability and pharmacokinetic data from these first-in-human studies for both of our novel pipeline candidates and we are continuing to advance them through phase 1," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "We recently initiated a multiple-ascending dose (MAD) study evaluating a 7-day dosing regimen for intravenous (IV) TP-6076 in healthy volunteers and we are on track to initiate a MAD study evaluating a 7-day dosing regimen for IV TP-271 in healthy volunteers during 2017. We are also evaluating an oral formulation of TP-271, which is currently in a single-ascending dose study."

Mr. Macdonald added, "Additional data presented at ASM Microbe on these two compounds confirm potent preclinical activity seen previously, particularly against Gram-negative pathogens. For TP-6076, the MIC₉₀ values reported were as much as 64-fold lower than those for tigecycline against MDR Gram-negative pathogens, including carbapenem-resistant *Enterobacteriaceae* and *Acinetobacter baumannii*. For TP-271, two *in vivo* studies were presented showing efficacy of TP-271 supporting its potential use in respiratory infections caused by *Acinetobacter baumannii* as well as its use as a countermeasure for the treatment of inhalation anthrax."

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

This oral presentation highlighted data from a phase 1 randomized, placebo-controlled, double-blind, single-ascending dose study evaluating the safety, tolerability and pharmacokinetics of IV TP-6076. The study was conducted at a single center in 40 healthy volunteers. Five sequential cohorts were randomized 6:2 to receive single doses ranging from 1.8 mg up to 60 mg, or placebo.

In this study, TP-6076 was well tolerated and there were no serious or severe adverse events, or discontinuations due to an adverse event. There were no clinically significant safety findings in any laboratory assessments, vital signs, ECGs or physical examinations. The most frequently reported adverse events in the TP-6076 groups were gastrointestinal, which consisted primarily of nausea in the highest dose group, no vomiting was reported. Following single IV doses of TP-6076, exposure to TP-6076 increased in a slightly greater than dose proportional manner.

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*.

Safety, Tolerability and Pharmacokinetics of Single Intravenous Doses of TP-271, a Novel Fluorocycline Antibiotic

This poster presentation described data from a phase 1 randomized, double-blind, placebo-controlled, single-ascending-dose, single-center study evaluating the safety, tolerability and pharmacokinetics of IV TP-271. The study was conducted at a single center in 56 healthy volunteers. Seven cohorts of 8 subjects each were randomized 6:2 to receive single doses ranging from 0.15 mg/kg up to 5 mg/kg, or placebo.

TP-271 was well tolerated at single doses that resulted in high plasma exposures. There were no clinically significant changes in lab values, ECG parameters, or physical exam findings. There were no serious or severe adverse events, or discontinuations due to an adverse event during the study. The most frequently reported adverse events in the TP-271 groups were gastrointestinal, which consisted of nausea and vomiting occurring mostly in the highest dose group. Following

single IV doses of TP-271, plasma exposures increased as dose increased in a greater than dose-proportional manner.

TP-271 is a novel, broad-spectrum antibiotic candidate which is being developed to combat respiratory disease caused by bacterial biothreats and antibiotic-resistant public health pathogens, including *Francisella tularensis*, *Yersinia pestis* and *Bacillus anthracis*, as well as bacterial pathogens associated with community-acquired bacterial pneumonia. Tetrphase is developing TP-271 with funding from the National Institutes of Health's National Institute of Allergy and Infectious Diseases, which supports preclinical development, manufacturing and phase 1 clinical, safety and pharmacokinetic evaluation of TP-271. In preclinical studies, TP-271 has demonstrated potency against Gram-negative and Gram-positive pathogens associated with respiratory tract infections.

ASM Microbe 2017 is the integration of two of the American Society of Microbiology's meetings: the General Meeting and ICAAC (Interscience Conference on Antimicrobial Agents and Chemotherapy). Requests for presentations can be sent to Medical Affairs through the Tetrphase website at <https://www.tphase.com/our-science/clinical-programs/>.

About Tetrphase Pharmaceuticals, Inc.

Tetrphase 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. Tetrphase has created more than 3,000 novel tetracycline analogs using its proprietary technology platform. Tetrphase's pipeline includes three antibiotic clinical candidates: eravacycline, which is 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.

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