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Tetraphase Pharmaceuticals Presents Clinical Data from Oral Eravacycline Development Program at IDWeek 2017

- Company plans to advance current oral eravacycline formulation into a phase 2 study in 1H18 -

WATERTOWN, Mass., Oct. 04, 2017 (GLOBE NEWSWIRE) -- Tetraphase Pharmaceuticals, Inc. (NASDAQ:TTPH), a clinical stage biopharmaceutical company developing novel antibiotics to treat life-threatening multidrug-resistant (MDR) infections, today announced the presentation of data at IDWeek 2017 from the first study of a recently completed phase 1 program designed to optimize drug exposure of oral eravacycline in an IV-to-oral dosing regimen. These results, along with data from subsequent trials in this phase 1 program, have allowed for the identification of an optimized IV-to-oral dosing regimen using the current oral formulation which the company plans to advance into a phase 2 clinical trial in patients with complicated urinary tract infections (cUTI). This study is anticipated to begin in the first half of 2018.

Eravacycline is a novel, fully-synthetic fluorocycline antibiotic being developed for the treatment of serious infections, including those caused by MDR pathogens. The IV eravacycline program includes two successfully completed phase 3 clinical trials in complicated intra-abdominal infections and an ongoing phase 3 clinical trial in cUTI. Separately, the oral eravacycline development program is ongoing and is designed to optimize and evaluate an IV-to-oral transition therapy of eravacycline.

"We are encouraged by the clinical data in healthy volunteers we have recently seen in the phase 1 oral eravacycline development program and are eager to initiate the next step of evaluating the optimized IV-to-oral dosing regimen in a patient population," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "In addition to establishing an oral dosing regimen, this phase 1 program has also confirmed that drug exposures and urine concentrations achieved with IV eravacycline are within the expected therapeutic range and support the efficacy of once-daily IV eravacycline in cUTI, which we are evaluating in the ongoing phase 3 IGNITE3 study. We look forward to topline data for IGNITE3 in the first quarter of 2018."

Patrick Horn, Chief Medical Officer of Tetraphase added, "Data from this phase 1 study presented at IDWeek confirm that the timing of oral dosing relative to meals drove the lower than expected drug exposures seen with the oral dosing regimen in IGNITE2, our first phase 3 IV-to-oral study in cUTI. Subsequent studies in this phase 1 oral program then evaluated different doses of eravacycline and varied meal time/dosing schedules. Results confirmed that increasing the interval between meals and dosing and administering a 250 mg oral dose of eravacycline produces drug exposures that we believe will be therapeutic in cUTI. With this optimized IV-to-oral dosing regimen, drug exposures achieved with the oral dose were 81% of those achieved with IV dosing, approximately double the exposure observed with the dosing regimen used in IGNITE2."

Dr. Horn continued, "We have also seen promising data in phase 1 clinical trials using a new oral eravacycline formulation and we will continue phase 1 development of this new formulation in parallel, as it could represent a future life-cycle option for oral eravacycline."

Study Design of the Phase 1 trial presented at IDWeek
This study evaluated the IV-to-oral dosing regimen and meal schedule that was used in the phase 3 IGNITE2 study. The objective was to assess plasma and urine levels achieved with that dosing regimen and compare these levels to those achieved using the same dosing regimen under fasted conditions. Sixteen healthy volunteers were enrolled in a cross-over study. Subjects were randomized 1:1 into either the fasted/fed or fed/fasted eravacycline treatment sequences. The dosing regimen was 1.5 mg/kg IV once daily on Days 1-3 and 200 mg oral twice daily, starting 12 hours after the Day 3 IV dose and continuing through Day 7. Plasma and urine samples for pharmacokinetic analysis were collected on Days 1, 3 and 7.

Study Results of the Phase 1 trial presented at IDWeek
In the fasted period, drug exposures on Day 7 were 65% of those achieved after the first IV dose, and both drug exposure and urine concentrations were in the expected therapeutic range. In the fed period, drug exposures on Day 7 were 39% of those achieved after the first IV dose, and both the drug exposure and urine concentrations were below the expected therapeutic range. The most commonly reported treatment-emergent adverse events (TEAEs) were nausea, vomiting, diarrhea and infusion site erythema, all of which were mild to moderate and occurred at rates similar to those observed in previous phase 1 studies with eravacycline. There were no discontinuations due to TEAEs.

About Eravacycline

Eravacycline is a novel, fully-synthetic fluorocycline antibiotic being developed for the treatment of serious infections, including those caused by multidrug-resistant (MDR) pathogens that have been highlighted as urgent public health threats by both the World Health Organization and the U.S. Centers for Disease Control (CDC). Eravacycline has demonstrated potent activity against multidrug-resistant (MDR) pathogens, including carbapenem-resistant Enterobacteriaceae (CRE), *Acinetobacter baumannii*, and colistin-resistant bacteria carrying the *mcr-1* gene. Eravacycline is in development for the treatment of complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI).

Eravacycline is currently being investigated in the Company's phase 3 IGNITE (**I**nvestigating **G**ram-**n**egative **I**nfections **T**reated with **E**ravacycline) program. To date, eravacycline has been administered to over 1,500 patients and in two completed phase 3 trials in cIAI. In IGNITE1, twice-daily IV eravacycline met the primary endpoint by demonstrating statistical non-inferiority of clinical response compared to ertapenem, was well tolerated, and achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates. The IGNITE1 data is serving as the basis of the Marketing Authorization Application for IV eravacycline for the treatment of patients with cIAI now under review by the European Medicines Agency. In IGNITE4, a 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, was well tolerated, and achieved high cure rates in patients with Gram-negative pathogens, including resistant isolates. The Company plans to use the results from IGNITE1 and IGNITE4 to support an NDA submission for IV eravacycline in cIAI in the first quarter of 2018. Tetraphase is also currently conducting IGNITE3, an additional phase 3 trial evaluating once-daily IV eravacycline in patients with cUTI and, assuming a positive outcome from IGNITE3 and approval of IV eravacycline for the treatment of cIAI, the Company plans to use the results from IGNITE3 to support a supplemental NDA submission for eravacycline in cUTI. In parallel, Tetraphase is continuing its efforts to develop an oral dose formulation of eravacycline. A clinical program is ongoing which is designed to optimize and evaluate the oral dosing regimen for eravacycline as part of an IV-to-oral transition therapy.

About Tetraphase Pharmaceuticals, Inc.
Tetraphase 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. Tetraphase has created more than 3,000 novel tetracycline analogs using its proprietary technology platform. Tetraphase's pipeline includes three antibiotic clinical candidates: eravacycline, which is in phase 3 clinical development, and 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 results obtained in previous clinical trials will be indicative of results obtained in future clinical trials; whether eravacycline will advance through the clinical trial process on a timely basis or at all; whether the results of the Company's development efforts will warrant regulatory submission and whether any such submissions will receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if any clinical candidate obtains approval, it will be successfully distributed and marketed; and other factors discussed in the "Risk Factors" section of our quarterly report on Form 10-Q, filed with the Securities and Exchange Commission on August 2, 2017. In addition, the forward-looking statements included in this press release represent our views as of October 4, 2017. 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 Contacts:
Tetraphase Pharmaceuticals
Teri Dahlman
617-600-7040
tdahlman@tphase.com

Argot Partners
Maeve Conneighton
206.899.4940
maeve@argotpartners.com

Media Contact:
Sam Brown Inc.
Mike Beyer
312-961-2502
Mikebeyer@sambrown.com

 Primary Logo

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