Tetraphase Pharmaceuticals Reports Fourth Quarter and Full-Year 2018 Financial Results and Highlights Achievements and Key 2019 Milestones

March 14, 2019

Conference Call Today at 4:30 p.m. Eastern Time

WATERTOWN, Mass.--(BUSINESS WIRE)--Mar. 14, 2019-- Tetraphase Pharmaceuticals, Inc. (NASDAQ:TTPH), a biopharmaceutical company focused on developing and commercializing novel tetracyclines to treat serious and life-threatening conditions, today reported financial results for the fourth quarter and year ended December 31, 2018, provided an overview of recent achievements, and highlighted key milestones for 2019.

"We capped off 2018 with a strong finish, with the regulatory approvals of XERAVA ™ (eravacycline) for the treatment of complicated intra-abdominal infections (cIAI) in both the U.S. and Europe, followed by the commercial launch of XERAVA in the U.S. in mid-October," said Guy Macdonald, President and Chief Executive Officer of Tetraphase. "With the U.S. launch off to a solid start, XERAVA is now available for use in U.S. hospitals and healthcare institutions for the treatment of a range of patients with empiric and confirmed cIAI. We are encouraged by the progress we have made during our first few months of launch, with more than 400 formulary reviews already completed or scheduled to occur by mid-year and a re-ordering rate for XERAVA above 70 percent. Further, as we look to the balance of 2019, we have made the decision to delay launching XERAVA in the EU5 independently and will instead continue to focus our resources on building momentum and supporting a successful launch in the U.S."

Mr. Macdonald continued, "With respect to our pipeline, we expect to complete our bronchopulmonary disposition study for TP-6076, targeted against *Acinetobacter baumannii* and other multidrug-resistant pathogens, later this year and look forward to presenting preclinical data on our new acute myeloid leukemia (AML) pipeline candidate, TP-2846, at the American Association for Cancer Research (AACR) Annual Meeting in Atlanta."

Key Milestones for 2019

- Complete 400 formulary reviews for XERAVA by mid-year
- Present preclinical data on TP-2846 at the AACR Annual Meeting – 2Q 2019
- Everest Medicines to begin Phase 3 clinical trial of eravacycline in cIAI in China – 2Q 2019
- Complete bronchopulmonary disposition study for TP-6076 – 2H 2019

Fourth Quarter and Recent Highlights

- **Commercially Launched XERAVA for cIAI in the U.S.**
  The Company commercially launched XERAVA in the U.S. in mid-October 2018. XERAVA is now available for use in hospitals and healthcare institutions for the treatment of a range of patients with empiric and confirmed cIAI. The salesforce is focusing on institutions responsible for treating 90 percent of patients with Gram-negative infections. Currently, three antimicrobial susceptibility tests (ASTs) have been approved for commercial use including the Eravacycline Mast Disk by Hardy Diagnostics; the Eravacycline MIC Strip by Liofilchem, Inc.; and the Sensititre Plate by Thermo Fisher Scientific, Inc. Previously, more than 200 healthcare institutions ordered ASTs for research-use-only purposes.

- **Received Marketing Authorization from the European Commission (EC) for XERAVA in the European Union (EU)**
  In September, the EC adopted the July 2018 positive opinion issued by the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) to grant marketing authorization for XERAVA for the treatment of cIAI in adults in all EU member states as well as Iceland, Liechtenstein and Norway.

- **Entered into Loan and Security Agreement with Solar Capital Limited**
  In November 2018, the Company entered into a loan agreement with Solar Capital Limited, providing up to $75 million, with $30 million funded at closing, which is being used to support the commercial launch of XERAVA and for general corporate purposes.

- **Announced New Preclinical Data on TP-2846 for AML to be Presented at the 2019 AACR Annual Meeting**
  In February 2019, Tetraphase announced it will present three posters on TP-2846, the Company's newly revealed pipeline candidate for AML, at the 2019 AACR Annual Meeting taking place March 29 – April 3 at the Georgia World Congress Center in Atlanta. The poster presentations will include *in vitro* and *in vivo* data supporting TP-2846's potential as a novel tetracycline antileukemia agent.

- **Approval of Everest Medicines' Investigational New Drug (IND) Application for Eravacycline in cIAI by the China National Medical Products Administration (NMPA)**
  In June 2018, Everest Medicines, a C-Bridge Capital-backed biopharmaceutical company, which has the exclusive license to develop and commercialize eravacycline in China, Taiwan, Hong Kong, Macau, South Korea and Singapore, submitted an IND application to the China NMPA, formerly the China FDA. The IND was approved by China NMPA, and Everest

expects to begin enrolling patients in its Phase 3 study of eravacycline in cIAI in the second quarter of 2019.

- **Presented XERAVA and TP-6076 Data at the Infectious Disease Society of America's (IDSA) 2018 IDWeek**
  In October 2018, the Company presented data related to XERAVA and TP-6076 at IDSA's IDWeek. Among the data presented were results from a post-hoc analysis of XERAVA Phase 3 data, which showed high clinical cure and microbiological eradication rates with XERAVA among patients with cIAI and concurrent bacteremia. Data from a Phase 1 randomized, placebo-controlled, double-blind, multiple-ascending-dose study demonstrating positive safety, tolerability and pharmacokinetic results for the Company's novel, fully synthetic tetracycline, TP-6076, were also presented.

- **Presented XERAVA Data at the American College of Clinical Pharmacy (ACCP) 2018 Global Conference**
  At the ACCP 2018 Global Conference in October, the Company announced positive data from a post-hoc analysis of two Phase 3 trials of XERAVA in cIAI in higher-risk populations – obese patients and those with altered renal function. Similar clinical cure rates were observed for XERAVA in these populations across all classifications of renal function, further supporting that the drug is an effective empiric treatment for cIAI and may provide an alternative to antibiotics that require dosing modification in patients with altered renal function. XERAVA was also effective regardless of body mass index when dosed 1mg/kg IV every 12 hours, based on total body weight when compared to carbapenems.

Fourth Quarter and Full-Year 2018 Financial Results

As of December 31, 2018, Tetraphase had cash and cash equivalents of $107.8 million and 53.7 million shares outstanding. The Company expects that its cash and cash equivalents, as well as expected revenue, will be sufficient to fund operations into the third quarter of 2020.

For the fourth quarter of 2018, Tetraphase reported a net loss of $21.5 million, or $0.40 per share, compared to a net loss of $23.5 million, or $0.46 per share, for the same period in 2017. For the year ended December 31, 2018, Tetraphase reported a net loss of $72.2 million, or $1.37 per share, compared to a net loss of $114.8 million, or $2.63 per share, for the same period in 2017.

XERAVA product revenue for the fourth quarter and year ended December 31, 2018 was $178,000, reflecting sales of the product which was commercially introduced in the U.S. in mid-October 2018.

Total revenues were $4.3 million for the fourth quarter of 2018, compared to $2.5 million for the same period in 2017. Total revenues were $18.9 million for the year ended December 31, 2018, compared to $9.7 million for the same period in 2017. Total revenues for the fourth quarter and year ended December 31, 2018 consisted of XERAVA product revenue, license and collaboration revenue from the Company's relationship with Everest Medicines and government contract revenue. The increases in total revenues for the fourth quarter and year ended December 31, 2018 compared to the same prior-year periods were primarily due to the collaboration and XERAVA revenue, neither of which existed in 2017.

Research and development (R&D) expenses for the fourth quarter of 2018 were $10.7 million, compared to $18.5 million for the same period in 2017. R&D expenses for the year ended December 31, 2018 were $54.9 million, compared to $101.7 million for the same period in 2017. The decreases in R&D expenses for the fourth quarter and year ended December 31, 2018 compared to the same prior-year periods were primarily due to lower clinical trial costs associated with the IGNITE Phase 3 clinical trials, which concluded in the first quarter of 2018, and a decrease in chemistry, manufacturing and controls (CMC) expenses for XERAVA.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2018 were $14.7 million, compared to $7.9 million for the same period in 2017. SG&A expenses for the year ended December 31, 2018 were $37.1 million, compared to $23.7 million for the same period in 2017. The increases in SG&A expenses for the fourth quarter and year ended December 31, 2018 compared to the same prior-year periods were primarily due to an increase in commercial launch-related expenses for XERAVA and related G&A infrastructure investments.

Conference Call and Webcast Information

Tetraphase will host a conference call today at 4:30 p.m. ET to discuss its financial results and provide an update on the Company. The call can be accessed by dialing 844-831-4023 (U.S. and Canada) or 731-256-5215 (international) and entering conference ID number 4187876. To access the live audio webcast, visit the "Investors — Events & Presentations" section of the Tetraphase website at www.tphase.com.

A replay of the conference call will be available from 7:30 p.m. ET on Thursday, March 14, 2019, through 7:30 p.m. ET on Thursday, March 21, 2019 and by dialing 855-859-2056 (U.S. and Canada) or 404-537-3406 (international). The conference ID number is 4187876. A replay of the webcast will be available on Tetraphase's website for 90 days.

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 program. 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.

XERAVA™ Important Safety Information

XERAVA is a tetracycline class antibacterial indicated for the treatment of complicated intra-abdominal infections in patients 18 years of age and older.

XERAVA is not indicated for the treatment of complicated urinary tract infections.

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.

XERAVA is contraindicated for use in patients with known hypersensitivity to eravacycline, tetracycline-class antibacterial drugs or to any of the excipients. 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 ≥ 3%) were infusion site reactions, nausea, and vomiting.

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 blood urea nitrogen, 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.

About Tetraphase Pharmaceuticals, Inc.

Tetraphase Pharmaceuticals, Inc., is a biopharmaceutical company using its proprietary chemistry technology to create novel tetracyclines for serious and life-threatening conditions, including bacterial infections 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, and TP-2846, which is in preclinical testing for acute myeloid leukemia. 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, including our key milestones for 2019 and our anticipated cash runway, 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 our commercial launch of XERAVA in the U.S. will be successful; our cash resources and the expected revenue will be sufficient to fund our operations for the period anticipated; our product candidates will succeed in clinical trials and even if the clinical trials are successful, we may never achieve regulatory approval of such product candidates and other clinical, regulatory and commercial risk factors discussed in the "Risk Factors" section of our quarterly report on Form 10-Q for the period ended September 30, 2018, filed with the Securities and Exchange Commission on November 9, 2018. In addition, the forward-looking statements included in this press release represent our views as of March 14, 2019. 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.

Tetraphase Pharmaceuticals, Inc.

Condensed Consolidated Statement of Operations (Unaudited)
(In thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Product revenue, net	$ 178	$ -	$ 178	$ -
License and collaboration revenue	3,177	-	12,677	-
Government revenue	928	2,528	6,049	9,666
Total revenue	4,283	2,528	18,904	9,666
Expenses:				
Cost of revenue - product	130	-	130	-
Cost of revenue - intangible asset amortization	98	-	98	-

Research and development	10,717	18,468	54,879	101,706
Selling, general and administrative	14,727	7,878	37,078	23,675
Total expenses	25,672	26,346	92,185	125,381
Loss from operations	(21,389)	(23,818)	(73,281)	(115,715)
Other income and expenses				
Interest income	532	343	1,747	963
Interest expense	(624)	-	(624)	-
Net loss	$ (21,481)	$ (23,475)	$ (72,158)	$ (114,752)
Net loss per share-basic and diluted	$ (0.40)	$ (0.46)	$ (1.37)	$ (2.63)
Weighted-average common shares used in net loss per share-basic and diluted	53,652	51,415	52,514	43,582

Tetraphase Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets (Unaudited)
(In thousands)

	December 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 107,776	$ 136,411
Accounts receivable, net	2,274	4,653
Contract asset	3,000	-
Inventory	748	-
Prepaid expenses and other current assets	2,674	6,382
Property and equipment, net	1,121	1,395
Intangibles assets, net	4,652	-
Other assets, noncurrent	699	199
Total assets	$ 122,944	$ 149,040
Liabilities and Stockholders' equity		
Accounts payable and accrued expenses	$ 14,957	$ 17,865
Deferred revenue	6	660
Loan payable	28,291	-
Other liabilities, noncurrent	8	105
Total stockholders' equity	79,682	130,410
Total liabilities and stockholders' equity	$ 122,944	$ 149,040

View source version on businesswire.com: https://www.businesswire.com/news/home/20190314005773/en/

Source: Tetraphase Pharmaceuticals, Inc.

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