Chiasma Reports Fourth Quarter and Year End 2017 Results

March 20, 2018

Chiasma Now Estimates Approximately 130 Patients Will Be Required to Enter Run-in Phase of MPOWERED Phase 3 Clinical Trial, Versus Previous Estimate of Up to 150 Patients

WALTHAM, Mass., March 20, 2018 (GLOBE NEWSWIRE) -- Chiasma, Inc. (NASDAQ:CHMA), a clinical-stage biopharmaceutical company focused on improving the lives of patients with rare and serious chronic diseases, today reported financial results for the fourth quarter and year ended December 31, 2017. Chiasma also announced it now estimates approximately 130 patients will be required to enter the 6-month run-in phase of its ongoing international MPOWERED Phase 3 clinical trial in order to randomize 80 octreotide capsule responders to the 9-month comparator phase. The Company previously estimated up to 150 patients would be required for the MPOWERED trial.

"We continue to make significant progress in our mission of advancing octreotide capsules as a maintenance treatment for adult patients with acromegaly," said Mark Fitzpatrick, president and CEO of Chiasma. "We are encouraged by the reduction in the estimated number of patients required to enter the run-in phase of the MPOWERED trial to reach target recruitment to the randomized 9-month comparator phase. We firmly believe in octreotide capsules, conditionally trade-named MYCAPSSA®, and we are excited to carry out the enrollment stages of our two Phase 3 clinical trials."

2018 Financial Guidance

Based on its current plans, Chiasma expects to have a cash and investment balance of at least $35 million at the end of 2018. The Company also expects that its existing cash and investments will be sufficient to fund its operations through the anticipated release of top-line data from the CHIASMA OPTIMAL clinical trial by the end of 2019 while supporting the MPOWERED trial in parallel.

CHIASMA OPTIMAL Phase 3 Trial

Chiasma is conducting a randomized, double-blind, placebo-controlled, nine-month clinical trial in 50 adult acromegaly patients (at least 20% of whom must be recruited from the United States) whose disease is biochemically controlled, based upon levels of IGF-1, a byproduct of increased growth hormone (GH) levels caused by acromegaly, on injectable somatostatin analogs at baseline (average IGF-1 ≤1.0 x upper limit of normal (ULN)). The patients also must have confirmed active acromegaly following their last surgical intervention based upon an elevated IGF-1 at that time of ≥1.3 x ULN. The trial is being randomized on a 1:1 basis to octreotide capsules or placebo. Patients are being dose titrated from 40 mg per day to up to a maximum of 80 mg per day, equaling two capsules in the morning and two capsules in the evening. Patients meeting predefined biochemical failure criteria in either treatment arm during the course of the trial will be considered treatment failures and revert to their original treatment of injections and will be monitored for the remainder of the trial. The primary endpoint of the study is the proportion of patients who maintain their biochemical response compared to placebo at the end of the nine-month, double-blind, placebo-controlled period as measured using the average of the last two IGF-1 levels ≤ 1.0 x ULN. Hierarchical secondary endpoints that will be considered by the FDA in evaluating the totality of evidence for octreotide capsules treatment effect include: proportion of patients who maintain GH response at week 36, compared to screening; time to loss of response of IGF-1 > 1.0 × ULN; time to loss of response of IGF-1 > 1.3 × ULN; change from screening to end of treatment in mean GH; and change in IGF-1 from baseline to end of treatment.

The FDA required that the last two secondary endpoints be analyzed by comparing the octreotide capsules treatment arm to the placebo treatment arm at the end of the nine-month, double-blind, placebo-controlled phase, including those patients that have been rescued by injectable somatostatin analogs. The Company estimates that as many as 90% or more of the placebo-treated patients may require rescue therapy.

MPOWERED ™Phase 3 Trial

Chiasma is conducting an international Phase 3 clinical trial under a protocol accepted by the European Medicines Agency (EMA) for the Company's octreotide capsules product candidate for the maintenance therapy of adult patients with acromegaly. The trial, referred to as MPOWERED (Maintenance of Acromegaly Patients with Octreotide Capsules Compared With Injections – Evaluation of REsponse Durability), is a global, randomized, open-label and active-controlled, 15-month trial. It now is expected to enroll approximately 130 adult acromegaly patients, of which it expects to randomize at least 80 patients who are responders to octreotide capsules following a six-month run-in to either octreotide capsules or injectable somatostatin receptor ligands (octreotide or lanreotide), and then followed for an additional nine months. The trial was initiated in March 2016 and is designed to evaluate the proportion of patients who maintain their biochemical response to octreotide capsules and patient-reported outcomes in patients treated with octreotide capsules, compared to patients treated with standard of care injectable somatostatin receptor ligands.

Based upon the first completed Phase 3 trial experience with octreotide capsules, the Company had previously estimated up to 150 patients would be required to enter the run-in phase of MPOWERED. Thus far, the aggregate number of patients withdrawing or not responding to octreotide capsules during the run-in phase is lower than originally expected. Chiasma announced in September 2017 that it had surpassed 50% patients randomized in the MPOWERED trial. The Company anticipates the release of top-line data from this Phase 3 clinical trial in 2020.

Fourth Quarter 2017 Financial Results

- **G&A Expenses**: General and administrative expenses were $1.8 million for the quarter ended December 31, 2017, compared with $2.5 million for the same period of 2016. The decrease was primarily due to the reductions in certain administrative functions.

- **R&D Expenses**: Research and development expenses were $4.3 million for the quarter ended December 31, 2017, compared with $4.8 million for the same period of 2016. The decrease was primarily due to certain manufacturing-related

costs of $0.4 million and reduced compensation-related costs and other research and development program efforts following the reductions of force in June and August 2016, which were partially offset by costs related to the initiation of the CHIASMA OPTIMAL clinical trial in September 2017.

- **Restructuring Charges**: Restructuring charges were $1.0 million for the quarter ended December 31, 2017, resulting from the lease termination of the Company's 24,000-square-foot office facility in Waltham, MA, compared with $0.6 million for the same period of 2016, which was attributable to the restructuring plan announced in August 2016.

- **Net Loss**: For the quarter ended December 31, 2017, net loss was ($6.1) million, or ($0.25) per basic share. This compares with a net loss of ($7.9) million, or ($0.32) per basic share, for the same period of 2016.

- **Cash Position**: Cash, cash equivalents and marketable securities as of December 31, 2017 were $66.9 million, compared with $93.0 million as of December 31, 2016, primarily reflecting the Company's operating expenditures for the 2017 fiscal year. The Company expects its existing cash, cash equivalents and marketable securities to fund operations through the anticipated release of top-line CHIASMA OPTIMAL data by the end of 2019 while supporting its MPOWERED trial in parallel.

About Chiasma

Chiasma is focused on improving the lives of patients who face challenges associated with their existing treatments for rare and serious chronic diseases. Employing its Transient Permeability Enhancer (TPE®) technology platform, Chiasma seeks to develop oral medications that are currently available only as injections. The Company recently initiated CHIASMA OPTIMAL, its third Phase 3 clinical trial for its octreotide capsules product candidate, conditionally trade-named MYCAPSSA®, for the maintenance therapy of adult patients with acromegaly in whom prior treatment with somatostatin analogs has been shown to be effective and tolerated following agreement with the FDA on the design of the trial. Chiasma is headquartered in Waltham, MA with a wholly owned subsidiary in Israel. MYCAPSSA, TPE and CHIASMA are registered trademarks of Chiasma. For more information, please visit the Company's website at www.chiasma.com.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the Company's development of octreotide capsules, conditionally trade-named MYCAPSSA, for the treatment of acromegaly, the Company's efforts to potentially obtain regulatory approval in the United States by conducting the Phase 3 CHIASMA OPTIMAL clinical trial under a Special Protocol Assessment, the Company's efforts to potentially obtain regulatory approval in Europe by conducting the ongoing MPOWERED Phase 3 clinical trial, the Company's estimate that 130 patients will be required for the MPOWERED trial to reach target recruitment in the trial, the timing of receipt and announcement of top-line and other clinical data and submission of regulatory filings, including the Company's ability to release top-line data from the CHIASMA OPTIMAL trial by the end of 2019 and the Company's ability to release top-line data from the MPOWERED trial in 2020, and the Company's cash forecasts, including its expected cash and investment balances as of the end of 2018 and the expectation that it has sufficient existing cash and investments on hand to fund its operations through its anticipated release of top-line data from the Phase 3 CHIASMA OPTIMAL clinical trial by the end of 2019 while supporting the MPOWERED trial in parallel. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Chiasma's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission (SEC) on March 20, 2018, and in subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Chiasma undertakes no duty to update this information unless required by law.

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Chiasma, Inc.
Condensed Consolidated Statements of Operations
(amounts in thousands except share and per share data)
(unaudited)

	For the three months ended		For the twelve months ended	
	December 31, 2017	December 31, 2016	December 31, 2017	December 31, 2016
Operating expenses:				
General and administrative	$ 1,793	$ 2,548	$ 9,146	$ 21,815
Research and development	4,323	4,791	17,948	31,317
Restructuring charges	1,038	605	1,038	8,179
Total operating expenses	7,154	7,944	28,132	61,311
Loss from operations	(7,154)	(7,944)	(28,132)	(61,311)
Other income, net	(160)	(158)	(716)	(547)

Loss before income taxes	(6,994)	(7,786)	(27,416)	(60,764)
Provision (benefit) for income taxes	(891)	109	(590)	347
Net loss	$ (6,103)	$ (7,895)	$ (26,826)	$ (61,111)
Earnings per share of common stock:				
Basic	$ (0.25)	$ (0.32)	$ (1.10)	$ (2.51)
Diluted	$ (0.25)	$ (0.32)	$ (1.10)	$ (2.51)
Weighted-average shares outstanding:				
Basic	24,378,930	24,359,584	24,366,681	24,319,443
Diluted	24,378,930	24,359,584	24,366,681	24,319,443

Chiasma, Inc.
Condensed Consolidated Balance Sheets Information
(amounts in thousands)
(unaudited)

	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 14,603	$ 37,013
Marketable securities	52,336	55,971
Prepaid expenses and other current assets	1,768	2,110
Property and equipment, net	193	683
Other assets	983	979
Total assets	$ 69,883	$ 96,756
Accounts payable	$ 1,017	$ 1,166
Accrued expenses	4,033	5,534
Other current liabilities	1,695	1,700
Long-term liabilities	664	2,631
Total liabilities	7,409	11,031
Total stockholders' equity	62,474	85,725
Total liabilities and stockholders' equity	$ 69,883	$ 96,756

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