Chiasma Reports Second Quarter 2019 Results

August 8, 2019

Announces positive data from Phase 3 CHIASMA OPTIMAL trial; MYCAPSSA®NDA submission expected by year-end 2019 with an expected six-month PDUFA review time period

MPOWERED enrollment complete; topline data expected in second half 2020

Completes common stock offering for net proceeds of $51.5 million

WALTHAM, Mass., Aug. 08, 2019 (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 second quarter ended June 30, 2019 and provided a business update.

In July, Chiasma announced positive topline data from CHIASMA OPTIMAL, its international Phase 3 clinical trial of MYCAPSSA® for the maintenance treatment of adults with acromegaly. The trial, which was conducted under a Special Protocol Assessment (SPA) agreement with the FDA, met the primary and all secondary endpoints. The primary endpoint was the percentage of patients on octreotide capsules compared to placebo who maintained their IGF-1 response through the 36-week core trial period **(58% of the patients on octreotide capsules compared to 19% of the patients on placebo, with a p-value of 0.008)**. In addition, the trial met all four of its secondary endpoints. Chiasma expects to submit an NDA by the end of the year, with an expected six-month PDUFA review time period.

"We are pleased with the CHIASMA OPTIMAL trial results as they are consistent with expectations from physicians based on treatment response rates demonstrated in prior acromegaly clinical trial results of somatostatin analogs. There is a significant momentum and a sense of urgency within the organization to get this novel innovative agent into the hands of patients that we expect could benefit from it," noted Raj Kannan, Chief Executive Officer of Chiasma. "In the CHIASMA OPTIMAL trial, 75% of the patients randomized to the octreotide capsules treatment arm completed the 36-week trial on study drug, and 90% of those patients voluntarily elected to continue into the open label extension. We believe this speaks to the strong preference by patients for an oral option and the potential for Mycapssa, if approved, to be a positive disruptive agent in the market."

During the second quarter, Chiasma announced that it had completed enrollment of 146 patients in its Phase 3 trial of MYCAPSSA®, known as MPOWERED™, which is designed to support approval in the European Union. The trial is progressing as planned, and the company anticipates releasing topline data in the second half of 2020.

Also, in July, Chiasma completed a follow-on public offering of 10,000,000 shares of its common stock that raised net proceeds of approximately $51.5 million, after deducting underwriting discounts, commissions and estimated offering expenses.

Second Quarter 2019 Financial Results

- **G&A Expenses:** General and administrative expenses were $2.6 million for the second quarter ended June 30, 2019, compared with $2.6 million for the same period of 2018. The current period results include increased professional services fees which were primarily offset by a reduction in legal costs.

- **R&D Expenses:** Research and development expenses were $5.5 million for the second quarter ended June 30, 2019, compared with $6.3 million for the same period of 2018. The decrease in clinical trial costs was partially offset by an increase in manufacturing costs.

- **Net Loss:** For the quarter ended June 30, 2019, net loss was ($7.8) million, or ($0.25) per basic share, compared with ($8.7) million, or ($0.36) per basic share, in the same period of 2018.

- **Cash Position:** Chiasma ended the second quarter with cash, cash equivalents and marketable securities of $58.1 million. In July, the Company completed a follow-on offering of common stock that raised net proceeds of approximately $51.5 million.

CHIASMA OPTIMAL Trial Design

The CHIASMA OPTIMAL trial was a randomized, double-blind, placebo-controlled, nine-month clinical trial of octreotide capsules that was conducted under a special protocol assessment, or SPA, agreement with the FDA. The trial enrolled 56 adult acromegaly patients whose disease was biochemically controlled by injectable somatostatin analogs (average IGF-1 ≤ 1.0 × upper limit of normal (ULN)). The patients also had confirmed active acromegaly following their last surgical intervention based upon an elevated IGF-1 at that time of ≥ 1.3 × ULN. Patients were randomized on a 1:1 basis, to octreotide capsules or placebo. Patients were 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 who met the predefined withdrawal criteria, or discontinued from oral treatment for any reason, in either treatment arm during the course of the trial were considered treatment failures and reverted to their original treatment of injections and monitored for the remainder of the trial. The primary endpoint of the trial was the proportion of patients who maintained their biochemical response 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 × ULN (assessed at weeks 34 and 36). Hierarchical secondary endpoints that are expected to be considered by the FDA in evaluating the totality of

evidence for octreotide capsules treatment include: proportion of patients who maintain GH response at week 36 compared to screening; time to loss of response: IGF-1 of 2 consecutive visits is > 1.0 × ULN; time to loss of response: IGF-1 of 2 consecutive visits is ≥ 1.3 × ULN; and proportion of patients requiring rescue treatment.

MPOWERED™ Phase 3 Trial

Chiasma is also conducting an international Phase 3 clinical trial under a protocol accepted by the EMA for the Company's octreotide capsules product candidate for the maintenance therapy of adult patients with acromegaly. The trial, referred to as MPOWERED, is a global, randomized, open-label and active-controlled, 15-month trial intended to support approval in the European Union. Chiasma completed enrollment of 146 adult acromegaly patients into the trial in June 2019, of which at least 80 patients who are responders to octreotide capsules per the protocol following a six-month run-in were randomized to either octreotide capsules or injectable somatostatin receptor ligands (octreotide LAR or lanreotide autogel), and then followed for an additional nine months. The trial 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. Chiasma expects to release top-line data from the MPOWERED Phase 3 clinical trial during the second half of 2020.

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. In July 2019, the Company reported positive topline data from its CHIASMA OPTIMAL 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. Prior to trial initiation, The Company reached agreement with the FDA on the design of the trial through a special protocol assessment. 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 named MYCAPSSA, for the treatment of acromegaly, the data from the CHIASMA OPTIMAL trial and whether the data will support the submission of an NDA for octreotide capsules and ultimately regulatory approval, statements regarding the timing of NDA submission and regulatory review, including the company's anticipated eligibility for a six-month PDUFA review cycle, statements concerning the nature of the FDA's review of any such NDA submission and whether the data submission will be sufficient to support regulatory approval, the Company's efforts to potentially obtain regulatory approval in the European Union by conducting the ongoing MPOWERED Phase 3 clinical trial, the timing of receipt and announcement of top-line and other clinical data and submission of regulatory filings, and the Company's ability to release top-line data from the MPOWERED trial during the second half of 2020. 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, 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.

Contact:
Ashley R. Robinson
LifeSci Advisors, LLC
617-535-7742
arr@lifesciadvisors.com

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

	For the three months ended		For the six months ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Operating expenses:				
General and administrative	$ 2,644	$ 2,627	$ 5,094	$ 5,061
Research and development	5,522	6,305	11,993	11,168
Total operating expenses	8,166	8,932	17,087	16,229
Loss from operations	(8,166)	(8,932)	(17,087)	(16,229)
Other income, net	(341)	(280)	(525)	(510)
Loss before income taxes	(7,825)	(8,652)	(16,562)	(15,719)
Provision (benefit) for income taxes	15	21	28	(3)
Net loss	$ (7,840)	$ (8,673)	$ (16,590)	$ (15,716)
Earnings per share of common stock:				
Basic	$ (0.25)	$ (0.36)	$ (0.59)	$ (0.64)
Diluted	$ (0.25)	$ (0.36)	$ (0.59)	$ (0.64)

Weighted-average shares outstanding:				
Basic	31,597,698	24,384,283	28,051,856	24,383,123
Diluted	31,597,698	24,384,283	28,051,856	24,383,123

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

	June 30, 2019	December 31, 2018
Cash and cash equivalents	$ 20,568	$ 13,060
Marketable securities	37,580	28,602
Insurance recovery	-	18,288
Prepaid expenses and other current assets	1,144	2,237
Property and equipment, net	96	111
Other assets	1,258	958
Total assets	$ 60,646	$ 63,256
Accounts payable	$ 3,256	$ 2,029
Estimated settlement liability	-	18,750
Accrued expenses	5,385	7,848
Other current liabilities	200	-
Long-term liabilities	676	505
Total liabilities	9,517	29,132
Total stockholders' equity	51,129	34,124
Total liabilities and stockholders' equity	$ 60,646	$ 63,256

Source: Chiasma, Inc.