Chiasma Provides Update on Ongoing Mycapssa® Phase 3 Clinical Trials

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On track with U.S. Phase 3 CHIASMA OPTIMAL trial; data now expected by mid-Q3 2019

Target enrollment completed in ongoing Phase 3 MPOWERED™ trial; data expected in 2H 2020

WALTHAM, Mass., June 27, 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 provided an update on the clinical development of its octreotide capsules product candidate, conditionally trade-named Mycapssa®, which is currently being evaluated in two ongoing, international Phase 3 clinical trials for the maintenance treatment of adults with acromegaly, the CHIASMA OPTIMAL and MPOWERED™ trials.

- In the Phase 3 CHIASMA OPTIMAL trial, which is being conducted under a special protocol assessment agreement, or SPA, with FDA, the company announced that the last enrolled patient completed the trial earlier this month. The company now expects to release top-line data by mid-Q3. Importantly, all 56 patients enrolled in the trial reached the final 36-week visit with no patient dropouts from the trial reported through the 36-week double-blind and controlled phase of the trial.

- In the MPOWERED™ Phase 3 clinical trial, which is designed to support approval in the European Union, the company also announced that it has also completed enrollment. In October 2018, after 80 patients were randomized into the nine-month controlled phase of the trial (from the 135 patients enrolled in the run-in phase), the company elected to resume enrollment in an effort to enroll additional patients exclusively located in the United States in order to gain further U.S. investigator and patient experience with octreotide capsules. Of the 146 total patients that have entered the six-month run-in phase, 84 patients (or greater than 60%) have completed the run-in phase of the trial and were randomized into the nine-month randomized controlled phase, while 10 patients currently remain active in the run-in phase.

"We are rapidly approaching a potentially transformational milestone for our company, with the anticipated release of CHIASMA OPTIMAL top-line data that, if positive, will support an NDA filing later this year," said Raj Kannan, Chief Executive Officer. "As we prepare for commercialization, we are encouraged by the positive feedback we have received from patients, physicians, and scientific experts on the value of an oral treatment alternative to the current standard of care, somatostatin analog injections. We look forward to potential U.S. approval of Mycapssa in mid-2020 as we advance toward our long-term goal of transforming the treatment paradigm for patients with acromegaly in the U.S. and around the world."

"Our two Phase 3 clinical trials of Mycapssa® are progressing as planned, and we look forward to reporting top-line data from CHIASMA OPTIMAL by mid-third quarter and MPOWERED™ in the second half of next year," said Gary Patou, MD, Head of Clinical.

William Ludlam, MD, PhD, Senior Vice President of Clinical Development and Medical Affairs, added, "There is a substantial body of evidence to suggest that current acromegaly treatments are burdensome for some patients and there remains a significant unmet medical need. We are grateful to the investigators and trial patients who helped to efficiently advance our clinical program to this point, and we look forward to the timely completion of these important trials."

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 June 2019, the company announced that the last enrolled patient completed 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. 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 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 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, including the Company's ability to release top-line data from the CHIASMA OPTIMAL trial in the third quarter of 2019, and if positive, to resubmit its NDA by year-end 2019, 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.

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