Chiasma Announces FDA Acceptance of MYCAPSSA® New Drug Application Resubmission

January 13, 2020

FDA sets PDUFA date of June 26, 2020

Acceptance follows December 26, 2019 NDA resubmission

NEEDHAM, Mass., Jan. 13, 2020 (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 announced that the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application (NDA) resubmission for its oral octreotide capsules investigational product candidate, conditionally trade named MYCAPSSA®. Chiasma is developing MYCAPSSA for the maintenance treatment of adults with acromegaly. The FDA assigned a Prescription Drug User-Fee Act (PDUFA) target action date of June 26, 2020, which is a six-month review.

"The FDA acceptance of our NDA resubmission marks the achievement of the first planned 2020 milestone for Chiasma and is a significant step towards making MYCAPSSA available to eligible patients," said Raj Kannan, Chief Executive Officer of Chiasma. "If approved, we believe MYCAPSSA, as the first oral somatostatin analog, has the potential to change the standard of pharmacological care in the management of patients with acromegaly. We look forward to working with the FDA during the review process towards a potential approval."

About Acromegaly

Acromegaly typically develops when a benign tumor of the pituitary gland produces too much growth hormone, ultimately leading to significant health problems. Common features of acromegaly are facial changes, intense headaches, joint pain, impaired vision and enlargement of the hands, feet, tongue and internal organs. Serious health conditions associated with the progression of acromegaly include type 2 diabetes, hypertension, respiratory disorders and cardiac and cerebrovascular disease. We believe that approximately 8,000 adult acromegaly patients are chronically treated with somatostatin analogs in the United States.

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. In January 2020, the FDA accepted the company's NDA resubmission seeking marketing approval of MYCAPSSA in the U.S. The PDUFA target action date is June 26, 2020. Chiasma is headquartered in Needham, 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, statements regarding the timing of regulatory review and potential approval, statements concerning the nature of the FDA's review of the NDA resubmission, statements concerning the commercial or therapeutic potential of MYCAPSSA, if approved, including the potential to change the standard of pharmacological care in the management of patients with acromegaly, and other statements that are not historical facts. Such statements are subject to numerous important factors, risks and uncertainties, many of which are beyond the company's control, that may cause actual events or results to differ materially from the company's current expectations. For example, there can be no guarantee that the FDA will agree that MYCAPSSA qualifies for marketing approval in the United States based on the results from the CHIASMA OPTIMAL trial and other information contained in the NDA. Management's expectations and, therefore, any forward-looking statements in this press release could be affected by risks and uncertainties relating to a number of factors. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the company's 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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