FDA Issues Complete Response Letter for Mycapssa™ New Drug Application

April 15, 2016

Company Hosting Conference Call on Monday at 8:30 a.m.

WALTHAM, Mass., April 15, 2016 (GLOBE NEWSWIRE) -- Chiasma, Inc. (NASDAQ:CHMA), a late-stage biopharmaceutical company focused on improving the lives of patients with rare and serious chronic diseases, today announced that it received a Complete Response Letter (CRL) from the United States (U.S.) Food and Drug Administration (FDA) regarding the company's New Drug Application for Mycapssa (octreotide) capsules for the maintenance treatment of U.S. adult patients with acromegaly. The FDA issues CRLs to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form. Chiasma is reviewing the FDA communication and plans to provide an additional update before market open on Monday, April 18, 2016.

Conference Call

At 8:30 a.m. Eastern Time on Monday, April 18, 2016, Chiasma's senior management team will host a conference call to discuss the FDA's decision. Investors can access a live and archived webcast of this call via the News & Investors section of the company's website, www.ChiasmaPharma.com. Individuals may also participate in the live call via telephone by dialing (877) 317-6789 (domestic) or (412) 317-6789 (international) and may access a teleconference replay for one week by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and using confirmation code 10084436.

About Mycapssa™

Mycapssa is an investigational new oral drug proposed for the maintenance therapy of adult patients with acromegaly. If approved, octreotide capsules may be the first oral somatostatin analog approved for acromegaly. Octreotide capsules have been granted orphan designation in the United States and the European Union for the potential treatment of acromegaly.

Octreotide capsules are an investigational drug that has not been approved for use in any jurisdiction.

About Chiasma

Chiasma is a late-stage biopharmaceutical company focused on improving the lives of patients suffering from orphan diseases by developing and commercializing novel oral forms of therapies that are available today only by injection. The company's lead product candidate is Mycapssa™ (octreotide) capsules, an investigational new drug developed with Chiasma's Transient Permeability Enhancer (TPE ®) technology to facilitate gastrointestinal absorption of unmodified drug into the bloodstream safely. Mycapssa™ is a proposed tradename, and this investigational new drug has not been approved for use in any jurisdiction. Using TPE® technology, Chiasma is evaluating additional proteins, peptides and small molecule drugs that are currently only available by injection but could potentially be converted to oral delivery. TPE® technology is potentially well suited for drugs with chronic indications, where frequent dosing is required and the need for an oral alternative is greatest. Chiasma is a Delaware corporation with a wholly-owned Israeli subsidiary. Mycapssa™ and TPE® are trademarks of Chiasma.

Additional information can be found at www.ChiasmaPharma.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 status of the company's NDA and the company's plans to review and comment on the FDA communication. 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. These risks and uncertainties include, but are not limited to: risks associated with the regulatory review process generally; risks associated with our Phase 3 clinical trial to support regulatory approval of Mycapssa in the E.U.; risks associated with obtaining, maintaining and protecting intellectual property; risks associated with Chiasma's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; the risk that octreotide capsules, if approved, will not be successfully commercialized; the risk of competition from currently approved therapies and from other companies developing products for similar uses; risk associated with Chiasma's ability to manage operating expenses and/or obtain additional funding to support its business activities; and risks associated with Chiasma's dependence on third parties . 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, 2015 filed with the Securities and Exchange Commission on March 17, 2016. 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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