Chiasma Announces U.S. Commercial Launch and Availability of MYCAPSSA®, the First and Only Oral Somatostatin Analog for Patients with Acromegaly

August 31, 2020

Chiasma advances U.S. commercial launch originally planned for fourth quarter

NEEDHAM, Mass., Aug. 31, 2020 (GLOBE NEWSWIRE) -- Chiasma, Inc. (NASDAQ: CHMA), a commercial stage biopharmaceutical company utilizing its delivery platform technology to develop oral therapies to reduce the burden of chronic injections for people with rare diseases, today announced the commercial launch and availability of MYCAPSSA® (octreotide) capsules in the United States for patients with acromegaly. MYCAPSSA, the first and only oral somatostatin analog (SSA), was approved by the U.S. Food and Drug Administration (FDA) on June 26, 2020 for the long-term maintenance treatment of patients with acromegaly who have responded to and tolerated treatment with octreotide or lanreotide.

"I am proud of our employees' tireless efforts to achieve the earlier-than-expected U.S. commercial launch of MYCAPSSA, the first and only oral SSA in an injectable dominated market," stated Raj Kannan, chief executive officer of Chiasma. "We are executing on our plan to make MYCAPSSA widely available to potentially address the strong preference by patients with acromegaly for an oral, non-medically administered therapy."

Anand Varadan, chief commercial officer of Chiasma, commented, "To support our launch of MYCAPSSA in the U.S., we have trained and deployed the first wave of what we believe is a world class sales team experienced in specialty, orphan diseases. Our team has been in the field since late July and we believe it is sized for and possesses the capabilities to operate in the current, predominantly remote environment. We plan to expand our customer-facing team as our commercial launch progresses and as we see the level of in-person interactions with healthcare providers increase. The initial feedback on MYCAPSSA from healthcare providers has been encouraging and we are continuing to engage with them to establish the foundation needed to execute a robust launch of MYCAPSSA."

About MYCAPSSA
INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE
MYCAPSSA (octreotide) delayed-release capsules, for oral use, is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

CONTRAINDICATIONS
Hypersensitivity to octreotide or any of the components of MYCAPSSA. Anaphylactoid reactions, including anaphylactic shock, have been reported in patients receiving octreotide.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions
MYCAPSSA can cause problems with the gallbladder. Monitor patients periodically. Discontinue if complications of cholelithiasis are suspected.

Blood sugar, thyroid levels, and vitamin B_{12} levels should be monitored and treated accordingly.

Bradycardia, arrhythmia, or conduction abnormalities may occur. Treatment with drugs that have bradycardia effects may need to be adjusted.

ADVERSE REACTIONS
The most common adverse reactions (incidence >10%) are nausea, diarrhea, headache, arthralgia, asthenia, hyperhidrosis, peripheral swelling, blood glucose increased, vomiting, abdominal discomfort, dyspepsia, sinusitis, and osteoarthritis.

DRUG INTERACTIONS
The following drugs require monitoring and possible dose adjustment when used with MYCAPSSA: cyclosporine, insulin, antidiabetic drugs, calcium channel blockers, beta blockers, lisinopril, digoxin, bromocriptine, and drugs mainly metabolized by CYP3A4. Counsel women to use an alternative non-hormonal method of contraception or a back-up method when MYCAPSSA is used with combined oral contraceptives.

Patients taking proton pump inhibitors, H2-receptor antagonists, or antacids concomitantly with MYCAPSSA may require increased dosages of MYCAPSSA.

PREGNANCY
Advise premenopausal females of the potential for an unintended pregnancy.

To report SUSPECTED ADVERSE REACTIONS, contact the product information department at 1-844-312-2462 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

The full Prescribing Information for MYCAPSSA is available at www.MYCAPSSA.com.

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. Chiasma estimates that approximately 8,000 adult acromegaly patients are chronically treated with somatostatin analog injections in the United States.

About Chiasma
Chiasma is focused on developing and commercializing oral therapies to improve 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. On June 26, 2020, Chiasma received FDA approval of MYCAPSSA for long-term maintenance therapy in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. MYCAPSSA is the first and only oral somatostatin analog approved by the FDA. 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 commercial launch and availability of MYCAPSSA, statements concerning the commercial or therapeutic potential of MYCAPSSA, the anticipated market acceptance of and access to MYCAPSSA, and statements concerning capabilities of our sales team and the potential hiring of additional customer-facing employees. 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. 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, including the following: the acceptance of MYCAPSSA in the commercial marketplace, the timing and costs involved in establishing a commercial organization, Chiasma's ability to obtain and maintain necessary regulatory approvals, and the impact the ongoing COVID-19 pandemic may have on the company's business, including its expected development, manufacturing, regulatory and commercialization timelines for MYCAPSSA. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, 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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