Chiasma Presents Positive Patient-Reported Outcomes Data from its MPOWERED™ Phase 3 Trial Comparing MYCAPSSA® to Long-Acting Injectables for the Maintenance Treatment of Adults with Acromegaly

May 27, 2021

--Data presented at AACE 2021 demonstrate patient quality of life and work productivity significantly improved in patients transitioning from injectable SSAs to MYCAPSSA®--

NEEDHAM, Mass., May 27, 2021 (GLOBE NEWSWIRE) -- Chiasma, Inc. (NASDAQ: CHMA), ("Chiasma" or the "Company") today presented patient-reported outcomes (PROs) data from its MPOWERED™ Phase 3 trial demonstrating that study patients with acromegaly reported significantly improved quality of life and work productivity after transitioning from long-acting injectable somatostatin analogs (iSSAs) to MYCAPSSA®. The data were shared as an oral presentation at the 30th Annual American Association of Clinical Endocrinology (AACE) Meeting being held virtually from May 26-29, 2021.

"The encouraging PROs data from the MPOWERED study further our understanding of the potential positive clinical impact that MYCAPSSA has for patients with acromegaly," said Nienke Biermasz, M.D., Ph.D., Presenting Author. "These PROs provide important information to help physicians assess disease and treatment burden for patients treated with iSSAs and may provide the confidence in MYCAPSSA as a treatment option that can be taken at home and also avoid some of the injection-related issues impacting quality of life and work productivity."

In the MPOWERED study, 146 patients entered the 6-month run-in phase in which all patients received MYCAPSSA. Ninety-two patients who were responders to MYCAPSSA at end of run-in were then randomized into the 9-month randomized controlled treatment (RCT) phase to receive MYCAPSSA or iSSAs. Among the 92 randomized patients, results showed that several PROs, including quality of life and work productivity, were significantly improved at the end of the run-in phase (reflecting outcomes on MYCAPSSA) compared to their results at the baseline of run-in (reflecting outcomes on iSSAs). Significant improvements were observed in the index scores of the EuroQol-5 Dimensions-5 Levels (EQ-5D-5L), a PRO developed to measure quality of life over five domains (mobility, ability to self-care, ability to undertake usual activities, pain and discomfort, and anxiety and depression; mean change from baseline of run-in to end of run-in, 0.053; 95% CI, 0.0130–0.0922). Significant improvements were also seen in comparing baseline of run-in to end of run-in on the Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP), a PRO developed to measure work and social activity in clinical trials, for presenteeism (impairment at work/reduced on-the-job effectiveness; least squares mean [LSM], –6.65; 95% CI,–12.39 to –0.90; P=0.024), work productivity loss (LSM, –6.92; 95% CI, –12.83 to –1.02; P=0.022) and activity impairment (LSM, –4.94; 95% CI, –9.17 to –0.71; P=0.022).

William Ludlam, M.D., Ph.D., Sr. Vice President, Clinical Development and Medical Affairs of Chiasma, added, "We are pleased to report data showing that MYCAPSSA represents a treatment option for acromegaly with the potential to positively impact patients whose lives may otherwise be significantly disrupted by injectable therapies. Taken together with the rest of the clinical data set we have generated for MYCAPSSA, these results further support our belief in MYCAPSSA's potential to become the new standard of pharmacological care for the maintenance treatment of acromegaly patients."

MPOWERED™ MYCAPSSA® Safety:
The safety profile of MYCAPSSA capsules in the MPOWERED trial was consistent with the known safety profile of octreotide but without adverse injection site reactions. No new or unexpected safety signals were detected during the study among MYCAPSSA subjects. See Important Safety Information below for contraindications, warnings, precautions and adverse reactions associated with MYCAPSSA based in the current approved labeling in the United States.

About the CHIASMA MPOWERED™ Trial
The MPOWERED™ trial was a global, randomized, open-label and active-controlled, 15-month trial intended to support approval of MYCPASSA® (oral octreotide capsules) in the European Union. This non-inferiority clinical trial was designed to compare MYCAPSSA to long-acting injectable somatostatin analogs (SSAs) for maintenance of biochemical response in patients with acromegaly. The trial enrolled 146 adult acromegaly patients of which 92 patients who were responders to MYCAPSSA after a six-month run-in phase were then randomized to a nine-month controlled (RCT) phase to either receive continued treatment on MYCAPSSA (n=55) or their prior injectable therapy (octreotide long-acting release or lanreotide autogel) (n=37). The primary endpoint of the trial was time-weighted average of IGF-1 <1.3 x upper limit of normal during the nine-month RCT phase. As previously announced, MPOWERED met its primary endpoint of non-inferiority compared to long-acting SSA injectables.

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 a commercial stage biopharmaceutical company 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. In June 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, the first and only oral somatostatin analog approved by the FDA, is available for commercial sale. 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 data from the MPOWERED trial, including, but not limited to, the patient reported outcomes data, statements regarding the company's expectations relating to MYCAPSSA for the long-term maintenance therapy in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide, and statements concerning the commercial or therapeutic potential of MYCAPSSA, including its ability to become a standard of care. 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 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 March 31, 2021, 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.

Investor Relations and Corporate Communications:
Ashley Robinson
LifeSci Advisors, LLC
617-430-7577
arr@lifesciadvisors.com

Media Relations:
Patrick Bursey
LifeSci Communications
646-876-4932
pbursey@lifescicomms.com

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