Chiasma to Host an Expert Panel on Acromegaly and the MPOWERED® Phase 3 Trial Results

November 20, 2020

NEEDHAM, Mass., Nov. 20, 2020 (GLOBE NEWSWIRE) -- **Chiasma, Inc. (NASDAQ: CHMA),** a commercial-stage biopharmaceutical company utilizing its delivery platform technology to develop and commercialize oral therapies to improve the lives of patients with rare diseases on burdensome and painful injections, today announced that it will host an expert panel on acromegaly and the results from its recently completed MPOWERED® Phase 3 clinical trial on Monday, November 30, 2020 at 11:00 am Eastern Time.

The call will feature presentations by Key Opinion Leader (KOL) Maria Fleseriu, MD, FACE, lead investigator of the MPOWERED study, who will discuss the topline data from Chiasma's Phase 3 MPOWERED study as well as the unmet medical need in acromegaly and the treatment burden that patients experience with monthly somatostatin analog injections. Additionally, a renowned patient advocate and Acromegaly Community President Jill Sisco will discuss the patient experience switching to MYCAPSSA®. Dr. Fleseriu and Ms. Sisco will be available to answer questions following the formal presentations.

Chiasma's management team will also provide an overview of the MPOWERED Phase 3 topline data, which were announced on November 18th. MPOWERED (Maintenance of acromegaly Patients with Octreotide capsules compared with injections – Evaluation of REsponse Durability), was a global, randomized, non-inferiority, open-label, and active-controlled 15-month trial that was designed to support a potential marketing application of MYCAPSSA® in the European Union.

This event is intended for institutional investors, sell-side analysts, and business development professionals only. To register for the call, please click here.

Maria Fleseriu, MD, FACE is a Professor of Medicine and Neurological Surgery and Director of the Pituitary Center at Oregon Health and Science University in Portland, Oregon and Immediate Past President of the Pituitary Society. Dr. Fleseriu has a long-standing clinical and research interest in the pathophysiology and treatment of pituitary and adrenal disorders. She is a frequent plenary guest speaker at national and international meetings on treatment of Cushing's, acromegaly and growth hormone deficiency, is global principal investigator in clinical trials, and has authored over 170 manuscripts in prestigious journals, including guidelines, consensus papers and book chapters.

Dr. Fleseriu has been awarded the title of "Doctor Honors Causa" by the University of Medicine and Pharmacy "Carol Davila" Bucharest, she serves on the Board of Directors and chairs Physician Education Committee for Pituitary Society, she serves on several committees for the Endocrine Society, Pituitary Society, and American Association of Clinical Endocrinology and she is past chair of the Endocrine Society Guidelines Committee and the Hypopituitarism task force.

Dr. Fleseriu is Chief Editor of Pituitary Endocrinology for Frontiers in Endocrinology, Section Head for Pituitary and Neuroendocrine F 1000, Associate Editor for European Journal of Endocrinology, Reviews in Endocrinology and Metabolism, Senior Editor for Endocrinology, Diabetes and Metabolism CR and a member of the editorial board of Pituitary. She has been involved in leadership positions of educational programs sponsored by the Endocrine Society, the Pituitary Society, and patient advocacy groups to teach physicians and patients about pituitary tumors and neuroendocrine disorders. She has served on multiple scientific advisory boards for biotechnology and pharmaceutical companies and participated in study design and has been global principal investigator for several Cushing's and acromegaly studies.

Dr. Fleseriu received her medical degree from the University of Medicine and Pharmacy, Timisoara, Romania and completed endocrinology training at University Hospital Sibiu, National Institute of Endocrinology "C.I Parhon" (with focus on pituitary disorders), Romania and Centre Hospitalier Luxembourg in Luxembourg. She pursued additional residency in internal medicine at Case Western Reserve University and an endocrinology fellowship at Cleveland Clinic in USA.

Jill Sisco is President of Acromegaly Community, Inc., a patient organization that helps educate patients and loved ones regarding this rare disease and provides guidance on how to cope with their difficult illness. Since her diagnosis in 2005, Jill has been an influential advocate towards a better quality of life for Acromegaly patients worldwide. In 2008, Jill became a leader in patient advocacy and has sat on several Acromegaly advisory boards. Jill has presented the patient perspective to FDA, co-authored several medical journal articles and abstracts regarding Acromegaly, and manages the widely visited patient community website and social media support groups. By organizing and hosting the biennial International Acromegaly Community Conference which engages patients, specialists, and pharmaceutical companies, Jill shows how passionate she is about providing an emotional and communal support network for people touched by acromegaly. She works tirelessly to enable forward thinking that will facilitate research, assist patients with their treatment plans, and provide positive outcomes for the future of acromegaly patients everywhere. Jill is highly respected in her community and has been a pioneer in building awareness around Acromegaly. Through her dedication, Jill leads by example and is a proponent of patients taking control of their lives and their disease and advocating for their best health possible.

MPOWERED™ Phase 3Clinical Trial
The MPOWERED trial was a global, non-inferiority, randomized, open-label and active-controlled, 15-month trial intended to support approval of MYCPASSA in the European Union. Chiasma completed enrollment of 146 adult acromegaly patients into the trial in June 2019, of which 92 patients were deemed responders to octreotide capsules per the protocol following a six-month run-in were randomized to either octreotide capsules (n=55) or injectable somatostatin receptor ligands (octreotide LAR or lanreotide autogel) (n=37), and then followed for an additional nine months. The trial was designed to evaluate the proportion of patients who maintain their biochemical response to octreotide capsules and patient-reported outcomes in patients treated with octreotide capsules, compared to patients treated with leading injectable somatostatin analogs.

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. 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, 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 and whether the data will support the submission of a marketing authorization application (MAA) to the European Medicines Agency (EMA) for MYCAPSSA in the European Union and ultimately regulatory approval. 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 content and timing of decisions made by the EMA, the sufficiency of the data collected from the company's clinical trials to obtain regulatory approval in the European Union or elsewhere, 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 September 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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