Chiasma Provides Corporate Update and Previews Expected 2021 Milestones

January 6, 2021

MYCAPSSA® launch in US continuing to gain traction with physicians, patients, and payers

MYCAPSSA® EMA submission for EU marketing approval on track for mid-2021 following positive results of MPOWERED Phase 3 clinical trial

NEEDHAM, Mass., Jan. 06, 2021 (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 currently treated with burdensome and painful injections, as evidenced by its recent phased launch of MYCAPSSA® as the first oral therapy for the treatment of acromegaly, today reviewed its 2020 accomplishments and previewed its anticipated 2021 corporate milestones.

2020 Key Highlights:

- **MYCAPSSA Approved in the U.S.** as the first and only oral somatostatin analog (SSA) for the long-term maintenance treatment of patients with acromegaly who responded to and tolerated treatment with octreotide or lanreotide.
    - Approval was based on the positive CHIASMA OPTIMAL Phase 3 trial results which were published in the Journal of Clinical Endocrinology & Metabolism and presented at the 2020 Endocrine Society Annual Meeting (ENDO) along with six other scientific posters relevant to MYCAPSSA.

- **Commercial Launch of MYCAPSSA in the U.S.** Late in the third quarter of 2020, Chiasma commenced the initial phase of the MYCAPSSA U.S. commercial launch with a focused salesforce calling on approximately one-third of key prescribing accounts. Chiasma progressed to the second phase of the launch at the beginning of 2021 with an expanded salesforce hired during the fourth quarter of 2020. Progression to the final phase of the launch with a full-strength salesforce is expected after market conditions improve beyond the COVID era.

- **Early launch insights and progress:**

    - Coverage of MYCAPSSA by multiple payers insuring approximately 150 million lives provides a solid foundation for MYCAPSSA uptake in 2021.
    - Positive and encouraging feedback on MYCAPSSA from endocrinologists and patients supports the company's goal of ultimately becoming the standard of pharmacological care in acromegaly.
    - Preliminary (unaudited) net revenues for 2020 are expected to be between $0.9 and $1.1 million.

- **Reported Positive Data from CHIASMA OPTIMAL Open Label Extension.** The efficacy and safety (tolerability) seen in the 1-year extension phase of the study (48 weeks) was similar to that seen in the 36-week core study period. The mean of the insulin-like growth factor 1 (IGF-1) levels for the population of all MYCAPSSA treated patients that completed the 36-week core CHIASMA OPTIMAL trial and continued into the open-label extension (OLE) (n=19) was maintained within normal limits at the end of the 48-week OLE period.

- **Reported Positive MPOWERED Phase 3 Topline Data.** The MPOWERED study met its primary non-inferiority endpoint. 91% of patients on MYCAPSSA maintained IGF-1 response (95% CI = 80%, 97%) compared to 100% on injectable SSAs (95% CI = 91%, 100%). The positive clinical trial results provide Chiasma a pathway to pursue regulatory approval of MYCAPSSA in the European Union (EU), further strengthen the available robust clinical data set for MYCAPSSA and provide additional meaningful information for healthcare providers in treating patients with acromegaly.

- **Strengthened Balance Sheet for U.S. Commercial Launch.** In April, Chiasma entered into a revenue interest financing agreement with HealthCare Royalty Partners (HCR) for up to $75 million. Also, in July, Chiasma raised approximately $75 million of net proceeds through an underwritten public offering of common stock and pre-funded warrants. Chiasma ended the year with approximately $135 million in cash, cash equivalents and marketable securities (exclusive of approximately $20 million of restricted cash), which is expected to fund its operations as currently planned through at least the end of 2021, including the execution of Chiasma's planned 2021 U.S. MYCAPSSA commercial launch strategy.

"2020 was the beginning of an important transformation for Chiasma from a company with a strong research and development foundation to a commercial-stage company," stated Raj Kannan, chief executive officer. "We are pleased with the progress of the MYCAPSSA launch to date and the encouraging feedback we have received from physicians, patients and payers. In 2021, we continue to build upon the MYCAPSSA launch in the United States while pursuing MYCAPSSA approval in the European Union. The recently reported positive MPOWERED clinical trial results further support our goal to make MYCAPSSA the new standard of pharmacological care in the long-term maintenance treatment of people with acromegaly."

Anticipated 2021 Milestones and Related Guidance:

- **Grow MYCAPSSA revenues in the U.S. by building on the progress made with the initial, focused selling effort in the first four months since launch:** Chiasma plans to drive adoption for MYCAPSSA with a broader group of physicians by expanding from a 36-person customer-facing team today to an approximately 45-person customer-facing team as market challenges associated with COVID-19 recede and payer coverage continues to expand.

- **MYCAPSSA EMA Submission.** In mid-2021, Chiasma plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) seeking regulatory approval to market MYCAPSSA to patients with acromegaly in the EU.

- **CHIASMA OPTIMAL Open Label Extension Data Oral Presentation at Virtual ENDO 2021.** Chiasma plans to present data on longer-term efficacy and safety of MYCAPSSA from the CHIASMA OPTIMAL trial's open-label extension at the virtual 2021 Endocrine Society Annual Meeting (ENDO), which is being held March 20-23.

- **Presentation of MPOWERED Phase 3 Data at Medical Conferences and Publication in a Peer Reviewed Medical Journal.** Chiasma expects to present MPOWERED Phase 3 data analyses at upcoming endocrinology scientific meetings in spring and in fall 2021 and submit the results of the MPOWERED trial to a peer-reviewed journal for expected publication in 2021.

- **2021 Financial Guidance.** Operating expense for the full year 2021 is expected to be in a range of $80 million to $90 million, including estimated stock-based compensation expense in a range of $5 million to $6 million. This guidance is based on the company's current U.S. commercial plans and excludes expenditure for potential EU launch preparations of MYCAPSSA and potential additional new product development programs.

2021 LifeSci Advisors Corporate Access Event
Chiasma management will be available to meet with institutional investors and analysts virtually at the 2021 LifeSci Advisors Corporate Access Event on January 7-8 and 11-14.

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 B12 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 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, the commercialization of MYCAPSSA, including efficiency improvements in processes for prescriptions and delivery of commercial product, the commercial or therapeutic potential of MYCAPSSA, including its ability to become a standard of care and the anticipated market acceptance and third-party reimbursement of and access to MYCAPSSA, the expansion of the customer-facing team, 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, the presentation and publication plans for the data from the MPOWERED trial, and the company's financial guidance, including operating expense and cash runway guidance. 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 FDA or EMA, the sufficiency of the data collected from the company's clinical trials to obtain regulatory approval in the European Union or elsewhere, the company's ability to retain requisite regulatory approvals for the commercial sale of MYCAPSSA in the United States, the timing and costs involved in establishing and maintaining a commercial organization and launching the sale of MYCAPSSA, 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.

Contacts:

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

CHIASMA