Chiasma to Present New Data from Two Phase 3 Trials, CHIASMA OPTIMAL and MPOWERED™, at ENDO 2021

March 10, 2021

-- One oral presentation and five late-breaking posters accepted --

NEEDHAM, Mass., March 10, 2021 (GLOBE NEWSWIRE) -- Chiasma, Inc. (NASDAQ: CHMA), ("Chiasma" or the "Company"), 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 approval of MYCAPSSA as the first and only oral therapy for the treatment of acromegaly, today announced that it will be presenting data from two Phase 3 clinical trials: the open-label extension of the CHIASMA OPTIMAL study and the MPOWERED™ study, at the Endocrine Society's annual meeting, ENDO 2021. The conference will be held virtually from March 20-23, 2021.

Chiasma is proud to be a platinum sponsor of the conference and will have a virtual booth available where registrants can find more information. The Company has also provided an unrestricted educational grant to support the continuing medical education (CME) program "Acromegaly: Novel Therapeutic Options to Alleviate Treatment Burden and Improve Patient Quality of Life" sponsored by Vindico Medical Education scheduled for Sunday, March 21 at 5:30 p.m. ET. This program will feature a faculty of experts and leaders in the pituitary and acromegaly space including Drs. Eliza Geer, Maria Fleseriu and Adriana Ioachimescu.

Abstracts selected for presentation are summarized below. The posters will be available online through April 30, 2021.

Oral Presentation
Title: One-Year Outcomes of the Open-Label Extension of CHIASMA OPTIMAL, a Phase 3 Study of Oral Octreotide Capsules in Acromegaly
Presenter: Susan L. Samson, M.D., Ph.D., FRCPC, FACE, Mayo Clinic in Florida
Session Date/Time: Monday, March 22, 2021, 2:30 p.m. – 2:40 p.m. EDT

Late-Breaking Poster Presentations
Title: Oral Octreotide Capsules Lowered Incidence and Improved Severity of Acromegaly Symptoms Compared to Injectable Somatostatin Receptor Ligands—Results from the MPOWERED Trial
Presenter: Nienke Biermasz, M.D., Ph.D., Leiden University Medical Center
Session Date/Time: Saturday, March 20, 2021, 11:00 a.m.-11:50 p.m. EDT

Title: Safety Results from MPOWERED, a Phase 3 Trial of Oral Octreotide Capsules in Adults with Acromegaly
Presenter: Pamela Freda, M.D., Columbia University
Session Date/Time: Saturday, March 20, 2021, 11:00 a.m.-11:50 p.m. EDT

Title: Improved Acromegaly Patient Satisfaction with Oral Octreotide Capsules Compared with Injectable Somatostatin Receptor Ligands in the MPOWERED Trial
Presenter: Murray B. Gordon, M.D., Allegheny General Hospital
Session Date/Time: Saturday, March 20, 2021, 11:00 a.m.-11:50 p.m. EDT

Title: A Phase 3 Large International Noninferiority Trial (MPOWERED): Assessing Maintenance of Response to Oral Octreotide Capsules in Comparison to Injectable Somatostatin Receptor Ligands
Presenter: Maria Fleseriu, M.D., FACE, Oregon Health & Science University Northwest Pituitary Center
Session Date/Time: Saturday, March 20, 2021, 11:00 a.m.-11:50 p.m. EDT

Title: Addition of Cabergoline to Oral Octreotide Capsules May Improve Biochemical Control in Patients with Acromegaly Who Are Inadequately Controlled with Monotherapy
Presenter: Maria Fleseriu, M.D., FACE, Oregon Health & Science University Northwest Pituitary Center
Session Date/Time: Saturday, March 20, 2021, 11:00 a.m.-11:50 p.m. EDT

To register and view the full schedule as well as abstracts, visit the Endocrine Society's website: www.endocrine.org/meetings-and-events/endo2021.

About the CHIASMA OPTIMAL Trial

The CHIASMA OPTIMAL trial was a randomized, double-blind, placebo-controlled, nine-month Phase 3 clinical trial of octreotide capsules that was conducted under a special protocol assessment (SPA) agreement with the FDA. The trial was designed to evaluate the proportion of patients who maintain their biochemical response to MYCAPSSA® (oral octreotide capsules) compared to placebo. The trial enrolled 56 adult acromegaly patients whose disease was biochemically controlled by injectable somatostatin analogs (octreotide or lanreotide) based upon levels of IGF-1, a byproduct of increased growth hormone (GH), levels caused by acromegaly (average IGF-1 ≤ 1.0 × upper limit of normal (ULN)). The patients also had confirmed active acromegaly following their last surgical intervention based upon an elevated IGF-1 at that time of ≥ 1.3 × ULN. Patients were randomized on a 1:1 basis, to octreotide capsules or placebo. The primary endpoint of the trial was the proportion of patients who maintained their biochemical response at the end of the nine-month, double-blind, placebo-controlled period as measured using the average of the last two IGF-1 levels ≤ 1.0 × ULN (assessed at weeks 34 and 36). Hierarchical secondary endpoints include: proportion of patients who maintain GH response at week 36 compared to screening; time to loss of response: IGF-1 of 2 consecutive visits is > 1.0 × ULN; time to loss of response: IGF-1 of 2 consecutive visits is ≥ 1.3 × ULN; and proportion of patients requiring reversion to prior treatment. As previously announced, CHIASMA OPTIMAL met the primary endpoint and all secondary endpoints.

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 MYCAPSSA® (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 randomized to a nine-month controlled phase with continued treatment on MYCAPSSA or on their prior injectable therapy. Patients were randomized to either MYCAPSSA (n=55) or injectable somatostatin receptor ligands (octreotide long-acting release or lanreotide autogel) (n=37), and then followed for an additional nine months. The primary endpoint of the trial was time-weighted average of IGF-1 <1.3 x upper limit of normal (ULN) during the nine-month randomized, controlled treatment (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 therapeutic potential of MYCAPSSA. 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. 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 Annual Report on Form 10-K for the year ended December 31, 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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