



## Chiasma to Present Encore and New Data from MPOWERED™ Phase 3 Trial at Upcoming e-ECE and AACE Virtual Conferences

May 20, 2021

*-- New clinical data accepted for oral and e-Poster presentation at AACE --*

*-- e-ECE clinical data previously presented at Endocrine Society's 2021 annual meeting --*

NEEDHAM, Mass., May 20, 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, today announced that it will virtually present encore data from its MPOWERED™ Phase 3 clinical trial at the 29<sup>th</sup> European Congress of Endocrinology (e-ECE) (May 22-26, 2021) and new data from the MPOWERED trial at the 30<sup>th</sup> Annual American Association of Clinical Endocrinology (AACE) Meeting (May 26-29, 2021).

### Oral presentations and posters for display are summarized below:

#### e-ECE 2021 Oral Presentation

**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, Professor, Medicine and Neurological Surgery, Director OHSU Northwest Pituitary Center

**Session Date/Time:** Wednesday, May 26, 2021, 8:30 a.m. – 9:30 a.m. EDT

#### e-ECE 2021 e-Poster Presentations

**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:** Monday, May 24, 2021, 8:00 a.m. – 8:30 a.m. EDT

**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:** Tuesday, May 25, 2021, 8:00 a.m. – 8:30 a.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, Professor, Medicine and Neurological Surgery, Director OHSU Northwest Pituitary Center

**Session Date/Time:** Tuesday, May 25, 2021, 8:00 a.m. – 8:30 a.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:** Wednesday, May 26, 2021, 8:00 a.m. – 8:30 a.m. EDT

#### AACE 2021 Oral Presentation

**Title:** Improved Quality of Life and Work Productivity in Patients with Acromegaly Receiving Oral Octreotide Capsules in the Phase 3 MPOWERED Trial

**Presenter:** Nienke Biermasz, M.D., Ph.D., Leiden University Medical Center

**Session Date/Time:** Thursday, May 27, 2021, 1:30 p.m. – 1:45 p.m. EDT

#### AACE 2021 Late-Breaker e-Posters - Available online via the virtual e-Poster Gallery beginning May 26

**Title:** Effects of Prior Injectable Somatostatin Receptor Ligand Type and Dose in Patients with Acromegaly Receiving Oral Octreotide Capsules in the Phase 3 MPOWERED Trial

**Lead Author:** Murray B. Gordon, M.D., Allegheny General Hospital

**Title:** Injection Site Reactions and Their Impact in Patients with Acromegaly Receiving Injectable Somatostatin Receptor Ligands in the Phase 3 MPOWERED Trial

**Lead Author:** Murray B. Gordon, M.D., Allegheny General Hospital

To register and view the full schedules as well as abstracts, visit e-ECE's website [here](#) and AACE's website [here](#).

Chiasma will sponsor a product theatre presentation at the AACE annual meeting titled "Understanding the Management of Acromegaly with MYCAPSSA® (octreotide) Delayed-Release Oral Capsules" on Wednesday, May 26 at 2:45 p.m. EDT. Anthony P. Heaney, M.D., Ph.D., Professor, UCLA, will lead the presentation and a live Q&A session.

#### About the MPOWERED™ Trial

The MPOWERED trial was a global, non-inferiority, randomized, open-label and active-controlled, 15-month trial intended to support approval of MYCAPSSA 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<sub>12</sub> 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, H<sub>2</sub>-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](http://www.fda.gov/medwatch)**

**The full Prescribing Information for MYCAPSSA is available at [www.MYCAPSSA.com](http://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<sup>®</sup>) 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](http://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 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 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.

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