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Michigan Revises Prior Authorization Criteria for Endari®

TORRANCE, Calif., Dec. 10, 2020 /PRNewswire/ --**Emmaus Life Sciences, Inc.** (OTC: EMMA), a leader in the treatment of sickle cell disease, announced today that it was notified by the Michigan Department of Health and Human Services (MDHHS) that the prior authorization criteria for Endari® was revised after being reviewed by Michigan's Medicaid Health Plan Common Formulary Workgroup. The MDHHS created the common formulary to streamline drug coverage policies for Medicaid and Healthy Michigan Plan beneficiaries and providers.

Effective January 1, 2021, the following two changes will be made regarding the initial authorization of Endari® for the treatment of sickle cell disease: (i) the history of Hydroxyurea use and adherence or intolerance/contraindication to Hydroxyurea will be eliminated from the Endari® initial authorization documentation requirements and (ii) "patient/family refusal" will be added to the existing justifications of intolerance or contraindication to the use of Hydroxyurea.

With this recent revision, MDHHS joins many other state health and human services agencies in eliminating the prior use of Hydroxyurea as a requirement for the initial authorization of Endari® for the treatment of sickle cell disease.

Endari®, Emmaus' prescription grade L-glutamine oral powder, was approved by the FDA in July 2017 for treating sickle cell disease in adult and pediatric patients five years of age and older. Sales of Endari® began in the United States in 2018.

"We greatly appreciate that the Michigan Department of Health and Human Services has modified the prior authorization criteria for Endari. These revisions, based on review and input from the Medicaid Health Plan Common Formulary Workgroup, will allow Endari to be prescribed to more of Michigan's sickle cell disease patients, more quickly, than under the current prior authorization criteria," said Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus. Dr. Niihara added, "Our goal is to provide Endari to all patients who may benefit from it as promptly as possible."

About Emmaus Life Sciences
Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company engaged in the discovery, development, marketing and sale of innovative treatments and therapies, including those in the rare and orphan disease categories. For more information, please visit www.emmausmedical.com.

About Endari® (prescription grade L-glutamine oral powder)
Indication - Endari is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older.

Important Safety Information
The most common adverse reactions (incidence >10 percent) in clinical studies were constipation, nausea, headache, abdominal pain, cough, pain in extremities, back pain, and chest pain.

Adverse reactions leading to treatment discontinuation included one case each of hypersplenism, abdominal pain, dyspepsia, burning sensation, and hot flash.

The safety and efficacy of Endari in pediatric patients with sickle cell disease younger than five years of age has not been established.

For more information, please see full Prescribing Information of Endari at: www.EndariRx.com/PI.

About Sickle Cell Disease
Sickle cell disease is an inherited blood disorder characterized by the production of an altered form of hemoglobin which polymerizes and becomes fibrous, causing red blood cells to become rigid and change form so that they appear sickle shaped instead of soft and rounded. Patients with sickle cell disease suffer from debilitating episodes of sickle cell crises, which occur when the rigid, adhesive and inflexible red blood cells occlude blood vessels. Sickle cell crises cause excruciating pain as a result of insufficient oxygen being delivered to tissue, referred to as tissue ischemia, and inflammation. These events may lead to organ damage, stroke, pulmonary complications, skin ulceration, infection and a variety of other adverse outcomes. Sickle cell disease is a significant unmet medical need, affecting approximately one hundred thousand patients in the U.S. and millions worldwide, the majority of which are of African descent. An estimated 1-in-365 African American children are born with sickle cell disease.

Forward-looking Statements
This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding the potential impact of revisions to the prior authorization criteria for Endari® in Michigan. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including uncertainties related to the future sales of Endari® in Michigan, Emmaus' working capital and ability to carry on its existing operations and obtain needed financing and up-listing of Emmaus' common stock and other factors previously disclosed in the company's reports filed with the Securities and Exchange Commission, and actual results may differ materially. Such forward-looking statements speak only as of the date they are made, and Emmaus assumes no duty to update them, except as may be required by law.

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