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FDA Approves Updated Label for Endari®

TORRANCE, Calif., Nov. 3, 2020 /PRNewswire/ --**Emmaus Life Sciences, Inc. (OTC: EMMA)**, a leader in sickle cell disease treatment, announced today revised prescribing information for Endari® to better inform healthcare professionals and sickle cell disease patients. Based on approval from the FDA, the updated label includes a statement that the clinical benefit of Endari® was observed irrespective of hydroxyurea usage and a new step-by-step instruction for use section at the end of the prescribing information.

"This label update provides important information to help clinicians make informed decisions on the use of Endari," said Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus. "We are particularly pleased with the FDA's acknowledgement that the clinical benefit of Endari is not affected by hydroxyurea use. That acknowledgement reinforces and supports the use of Endari as a monotherapy or in combination with hydroxyurea as important treatment options for patients with sickle cell disease."

Endari® was approved by the FDA in July 2017 for the treatment of sickle cell disease in adult and pediatric patients five years of age and older and sales began in 2018.

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 updated prescribing information for Endari®. 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®, 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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