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Emmaus Life Sciences Announces Submission of Marketing Authorization Application for Endari® to the Saudi Food & Drug Authority

TORRANCE, Calif., May 26, 2021 /PRNewswire/ -- Emmaus Life Sciences, Inc. (OTC: EMMA), a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease, announced today that its application for Marketing Authorization (MA) for Endari® in the Kingdom of Saudi Arabia has been accepted by the Saudi Food and Drug Authority (SFDA). The SFDA's MA review and approval process typically takes 12 to 18 months. Endari®, Emmaus' prescription grade L-glutamine oral powder, is approved by the United States Food and Drug Administration for treating sickle cell disease in adult and pediatric patients five years of age and older.

It is estimated that up to 1.4% of the total population of 35 million in the Kingdom of Saudi Arabia have sickle cell disease. During the SFDA's MA review and approval process, Endari® will be available to sickle cell disease patients on an early access basis to address an unmet medical need. Emmaus estimates that there are approximately 225,000 sickle cell disease patients that are reachable and could potentially be treated with Endari® throughout the Middle East and North Africa (MENA) region.

"This submission and acceptance of our marketing authorization application by the Saudi Food & Drug Authority is another significant step in our progress and commitment to serve sickle cell disease patients in the MENA region," said Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus.

George Sekulich, Senior Vice President of Global Commercialization of Emmaus, added, "We look forward to continue building and enhancing our relationships with the hematologists and patient advocacy groups in the Kingdom of Saudi Arabia. Emmaus is also working with clinicians on providing Endari on a named-patient basis in the Kingdom and the wider MENA region."

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 early access and possible marketing approval of Endari® in the Kingdom of Saudi Arabia. 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 the Kingdom of Saudi Arabia and the MENA region 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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