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Emmaus Life Sciences Announces Submission of Marketing Authorization Application to the Saudi Food and Drug Authority

TORRANCE, Calif., Aug. 18, 2020 (GLOBE NEWSWIRE) -- **Emmaus Life Sciences, Inc. (OTCPK: EMMA)**, a leader in sickle cell disease treatment, announced today the submission of an application to the Saudi Food and Drug Authority (SFDA) for Marketing Authorization (MA) for Endari® in the Kingdom of Saudi Arabia. This follows Emmaus' announcement that the SFDA had granted Endari® a priority review designation as part of its program to expedite the review of drugs that are expected to have a significant impact on the treatment of a disease with unmet medical need. Endari®, Emmaus' prescription grade L-glutamine oral powder, is approved by the United States FDA and the Israeli Ministry of Health to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older.

Endari® can currently be prescribed in Saudi Arabia on a named patient basis and will continue to be available on that basis during the review and approval process with the SFDA. Emmaus estimates that there are approximately 225,000 sickle cell disease patients that could potentially be treated with Endari® in the Middle East and North Africa (MENA) region. Saudi Arabia has the highest prevalence of sickle cell disease in the MENA region with an estimated 100,000 treatable patients.

Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus, stated, "We are pleased with the progress we continue to make in the MENA region and look forward to the SFDA's review of our MA application. With the opening of our office in Dubai, expedited review previously granted by the SFDA and now the submission of our MA application, we are gratified to be in a position to improve the lives of the sickle cell disease patients in Saudi Arabia."

George Sekulich, Senior Vice President of Global Commercialization of Emmaus, added, "Emmaus is excited to bring Endari® to Saudi Arabia and will continue to enhance our partnerships with the hematologists and patient advocacy groups across the MENA region to serve the patients and their families afflicted with sickle cell disease in the best way 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® (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.ENDARlrx.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 patient access to Endari®. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including uncertainties relating to possible future marketing approval in Saudi Arabia and the MENA region and Emmaus' working capital and ability to carry on its existing operations and obtain needed financing 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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