

April 16, 2020



# Emmaus Life Sciences Announces SFDA (Saudi Food & Drug Authority) Accepts Endari® Priority Review Request

TORRANCE, Calif., April 16, 2020 (GLOBE NEWSWIRE) -- **Emmaus Life Sciences, Inc. (OTCQB: EMMA)**, a leader in sickle cell disease treatment, announced today that the SFDA (Saudi Food & Drug Authority) has accepted its request for priority review of Endari®, its prescription grade L-glutamine oral powder. Similar to the U.S. Food & Drug Administration (FDA), priority review by the SFDA in Saudi Arabia is a program designated to expedite the review process for drugs that are expected to have a particularly significant positive impact on the treatment of a disease.

Saudi Arabia has the highest prevalence of sickle cell disease in the MENA (Middle East, North Africa) region. Emmaus estimates that there are approximately 225,000 sickle cell disease patients that could potentially be treated with Endari® in that region.

Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus, stated, “We are pleased that the SFDA has accepted our priority review request for Endari®. Emmaus sincerely thanks the SFDA for its recognition of the urgency to make effective and safe therapy available for sickle cell disease patients. We will present our study data that led to the FDA’s approval along with additional data and patient experience since the FDA’s approval of Endari® for the SFDA’s review.”

George Sekulich, Senior Vice President of Global Commercialization of Emmaus, further commented, “This decision by the SFDA is welcomed and represents a significant step in providing Endari® to sickle cell disease patients both in Saudi Arabia and throughout the entire MENA region. Additionally, Emmaus will continue to provide the drug through its early access program for patients and clinicians in the Gulf Cooperation Countries.”

## **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](http://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.ENDARIRx.com/PI](http://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 patient access to Endari<sup>®</sup>. 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 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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Source: Emmaus Life Sciences