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Emmaus Life Sciences Announces Bahrain Temporary License of Endari®

License Permits Importation and Early Access to Patients Pending Marketing Authorization

TORRANCE, Calif., Aug. 17, 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 on August 12, 2021, the National Health Regulatory Authority (NHRA) of the Kingdom of Bahrain approved a Temporary License for Importation of Pharmaceutical Product for Endari.® The Pharmaceutical Products Regulation Department of the NHRA is responsible for ensuring the quality, safety, and efficacy of pharmaceutical products in the Kingdom of Bahrain. 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.

With a total population of 1.8 million, the incidence of sickle cell disease in the Kingdom of Bahrain is estimated at 2.1%. Emmaus is in the process of applying for marketing authorization for Endari.® In the meantime, the NHRA approval permits the importation of Endari in the Kingdom for up to 12 months to treat 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.

"We are pleased that the NHRA has approved Endari on a temporary basis. Along with the submission of our marketing authorization applications to the Saudi Food and Drug Authority and the Kuwait Food and Drug Control earlier this year, the temporary license approval is another important step in our meeting our 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,

"While we prepare our first shipment of Endari to our distributor in Bahrain, we are working to build our relationships with the hematologists and patient advocacy groups in the Kingdom. In addition, Emmaus continues collaborating with clinicians on providing Endari on a named-patient basis in the Bahrain 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
There are approximately 100,000 people living with sickle cell disease (SCD) in the United States and millions more globally. The sickle gene is found in every ethnic group, not just among those of African descent; and in the United States an estimated 1-in-365 African Americans and 1-in-16,300 Hispanic Americans are born with SCD.[1] The genetic mutation responsible for SCD causes an individual's red blood cells to distort into a "C" or a sickle shape, reducing their ability to transport oxygen throughout the body. These sickled red blood cells break down rapidly, become very sticky, and develop a propensity to clump together, which causes them to become stuck and cause damage within blood vessels. The result is reduced blood flow to distal organs, which leads to physical symptoms of incapacitating pain, tissue and organ damage, and early death.[2]

[1]Source: Data & Statistics on Sickle Cell Disease – National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, December 2020.

[2]Source: Committee on Addressing Sickle Cell Disease – A Strategic Plan and Blueprint for Action -- National Academy of Sciences Press, 2020.

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 potential marketing approval of Endari® in the Kingdom of Bahrain. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including uncertainties related to marketing approval in the Kingdom of Bahrain and elsewhere in the MENA region and other factors previously disclosed in the company's most recent Annual Report on Form 10-K/A 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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