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Emmaus Life Sciences Announces Submission of Endari® Marketing Authorization Application in Kuwait

TORRANCE, Calif., July 15, 2021 /PRNewswire/ --**Emmaus Life Sciences, Inc. (OTC: EMMA)**, a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease, announced today the submission of its application for Marketing Authorization (MA) for Endari® to the Kuwait Drug and Food Control (KDFC). This is the first step in the registration of Endari® by the KDFC, which is responsible for the registration of pharmaceutical products in Kuwait. The KDFC has accepted Emmaus's request for fast-track review of Endari®, which is expected to take not more than twelve 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.

Although there are only an estimated 500 sickle cell disease patients in Kuwait, sickle cell disease remains a significant unmet medical need in the country, and during the KDFC's review, Endari® will be available to sickle cell disease patients on an early access basis to address this unmet need.

"We are pleased to announce the submission of our marketing authorization application to the Kuwaiti authorities. Along with the submission of our marketing authorization application to the Saudi Food and Drug Authority announced in May 2021 it represents another important milestone in our progress and commitment to serve sickle cell disease patients in the Middle East and North Africa 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 continue to work on building relationships with hematologists and patient advocacy groups and collaborating with clinicians to provide Endari on a named-patient basis in Kuwait and the greater 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 possible marketing approval of Endari® in Kuwait. 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 Kuwait and the greater 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.

Company Contact:
Emmaus Life Sciences, Inc.
George Sekulich
Chief Information Officer & Senior Vice President of Global Commercialization
(310) 214-0065 x1010
gsekulich@emmauslifesciences.com

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