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Emmaus Life Sciences Receives Marketing Authorization for Puerto Rico

TORRANCE, Calif., Feb. 2, 2024 /PRNewswire/ -- **Emmaus Life Sciences, Inc. (OTCQX: EMMA),** a leader in sickle cell disease (SCD) treatment, today announced that it has received marketing authorization from the Puerto Rico Department of Health for Endari® (L-glutamine oral powder). This approval marks a significant milestone in Emmaus' mission to improve the lives of people with SCD around the world and provides access to this important therapy for the patients living with SCD in Puerto Rico. In addition, Endari® is approved in the United States, Israel, United Arab Emirates, Kuwait, Qatar, Bahrain, and Oman.

"We are thrilled to bring Endari® to Puerto Rico, where the SCD community has faced significant challenges in accessing innovative treatments," said George Sekulich, Co-President of Emmaus Life Sciences. "This approval is a testament to our commitment to working with regulatory authorities and patient advocacy groups to expand access to Endari® for all who need it."

Endari® is the first FDA-approved oral glutamine therapy for the reduction of acute complications of SCD in adult and pediatric patients five years and older. Clinical studies have shown that Endari® can significantly reduce the frequency of pain crises, hospitalizations, and other acute complications of SCD.

Emmaus is committed to working with healthcare providers and payers in Puerto Rico to ensure that Endari® is accessible to all eligible patients. The company is also working to raise awareness of SCD and the benefits of Endari® through educational programs for healthcare providers and patients.

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. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including the risk that the authorization does not lead to significant sales of Endari® in Puerto Rico and uncertainties related to 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.

Company Contact:
Emmaus Life Sciences, Inc.
Willis Lee

Co-President and Chief Operating Officer
(310) 214-0065, Ext. 1130
wlee@emmauslifesciences.com

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