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Endari® Receives Kuwaiti Marketing Authorization

Kuwait is Third Gulf Cooperation Council Country to Approve Endari®

TORRANCE Calif., Dec. 7, 2022 /PRNewswire/ -- **Emmaus Life Sciences, Inc.** (OTCQX: EMMA), a leader in sickle cell disease treatment, announced today that it has received Registration Approval from the Pharmaceutical and Herbal Medicines Registration and Control Administration (Drug and Food Control) of the Kuwaiti Ministry of Health granting marketing authorization for the commercial distribution and sale of Endari® in the country.

Kuwait is the latest Gulf Cooperation Council (GCC) country to grant full marketing approval for Endari® following approvals in the United Arab Emirates and the State of Qatar earlier this year.



Endari® is approved in the U.S. and elsewhere to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older. Endari® is available on an early access basis in Bahrain and the Kingdom of Saudi Arabia pending official notice of action on Emmaus's marketing authorization applications in those countries.

Dr. Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus, commented, "We continue to see progress in our mission to make Endari available to the many sickle cell patients in the GCC countries and are grateful to the Kuwaiti officials for this latest marketing approval." Dr. Niihara added, "We are hopeful that sales in the region and increased domestic sales will help us to generate positive operating cash flows beginning in 2023."

George Sekulich, Senior Vice President of Global Commercialization of Emmaus, added, "Receiving the approval to market Endari in Kuwait is another critical step forward for Emmaus, patients in the region, and clinicians. We look ahead to expanding our presence in this market and continuing working with our trusted partners."

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.ENDARlrx.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

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

²Source: 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 the potential future sales of Endari in Kuwait and other GCC countries. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including the risk that the Registration Approvals in Kuwait and other GCC countries do not result in significant sales of Endari® in the region

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.

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