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Emmaus Life Sciences Receives Endari® Marketing Authorization from the Bahrain NHRA

TORRANCE, Calif., May 31, 2023 /PRNewswire/ -- **Emmaus Life Sciences, Inc.** (OTCQX: EMMA), a leader in sickle cell disease treatment, announced today that it has received a Medicine Registration Certificate (DRN-10164/23) from the Bahrain National Health Regulatory Authority (NHRA) granting marketing authorization for the commercial distribution and sale of Endari® in the Kingdom of Bahrain.

Endari® is approved in the U.S., the United Arab Emirates, Israel, Kuwait, the State of Qatar and Bahrain to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older.

Dr. Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus, commented, "We are grateful that Bahrain officials have seen fit to make Endari available to sickle cell patients in the country. It furthers our mission to afford increased access to Endari in the Middle East and North Africa region, as well as in India, with their large and underserved sickle cell disease patient populations."

George Sekulich, Senior Vice President of Global Commercialization of Emmaus, added, "The approval from the NHRA is further validation of the safety and efficacy of Endari. We look forward to working with our partner, Gulf Pharmacies, to make Endari available to the sickle cell disease patients in the country. Also, we are expecting final action on our application in the Kingdom of Saudi Arabia, where Endari® is currently available on an early access basis only."

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 the availability of Endari to sickle cell disease patients in Bahrain and possible action by the Saudi FDA. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including the risks that the marketing authorization does not result in significant sales of Endari® in Bahrain and that the application for Saudi marketing authorization is not approved, as well as 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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