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## Emmaus Life Sciences Submits Application for U.A.E. Marketing Authorization for Endari®

TORRANCE, Calif., Oct. 26, 2021 /PRNewswire/ --**Emmaus Life Sciences, Inc. (OTC: EMMA)** a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease, today announced the submission of its application for marketing authorization of Endari® to the United Arab Emirates (U.A.E.) Ministry of Health. Review of the application is expected to take 10 to 12 months. During the review period, Endari may be prescribed in the U.A.E. on a named patient, or early access, basis.



Emmaus estimates that as many as 600 sickle cell disease patients live or work in the U.A.E. and approximately 225,000 sickle cell disease patients throughout the Middle East North Africa (MENA) region who could potentially be treated with Endari.

"This U.A.E application submission is the first of several full marketing applications we expect to file in Gulf Cooperation Council states for Endari, to treat the numerous sickle cell disease patients in the MENA region," stated 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 look forward to working with the U.A.E Ministry of Health to bring this important medication to our patient population in the Emirates. In the meantime, Endari continues to be available on a named patient basis throughout the MENA region."

### **About Emmaus Life Sciences**

Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease. The company currently markets U.S. Food and Drug Administration approved Endari® (L-glutamine oral powder) indicated to reduce the acute complications of sickle cell disease in adults and children 5 years and older. The company is also engaged in the discovery and development of innovative treatments and therapies for certain rare and orphan diseases as well as those affecting larger populations, such as diverticulosis. For more information, please visit [www.emmausmedical.com](http://www.emmausmedical.com).

## **About Endari® (prescription grade L-glutamine oral powder)**

Endari®, Emmaus' prescription grade L-glutamine oral powder, was approved by the FDA in July 2017 for treating sickle cell disease in adult and pediatric patients five years of age and older. Sales of Endari® began in the United States in 2018.

## **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](http://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.<sup>1</sup> 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.<sup>2</sup>

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

<sup>2</sup>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 possible eventual marketing approval of Endari® in the U.A.E. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including risks inherent in the regulatory approval process and other factors previously disclosed in the company's Annual Report on Form 10-K/A filed with the Securities and Exchange Commission (SEC) on August 10, 2021 and other SEC reports, 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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