

# Emmaus Life Sciences Receives Marketing Authorization for Endari® in Oman

Sickle Cell Disease Treatment Commercially Available in Five GCC Countries

TORRANCE, Calif., July 13, 2023 /PRNewswire/ -- Emmaus Life Sciences, Inc. (OTCQX: EMMA), a leader in sickle cell disease treatment, today announced that it has received marketing authorization from the Oman Ministry of Health for the commercial distribution and sale of Endari® (L-glutamine oral powder) in the country to treat sickle cell disease in patients five years of age and older.



There are around 3,000 patients with sickle cell disorders in Oman<sup>1</sup>. The birth prevalence of infants with hemoglobin disorders was 3.5-4.7 per 1,000. Around 6% of Omanis are carriers of the gene for sickle cell anaemia <sup>1</sup>.

"We are delighted to receive marketing authorization for Endari® in Oman, where sickle cell disease is a significant public health issue that affects thousands of patients and their families," said Dr. Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus. "This approval marks another milestone in our mission to improve the lives of people with sickle cell disease around the world."

"The Omani marketing approval for Endari is an important step forward for us in the GCC region, where we have been working closely with the local authorities, physicians, and patient groups to ensure access to this innovative treatment for sickle cell disease," said George Sekulich, Senior Vice President of Global Commercialization of Emmaus Life Sciences, Inc. "We look forward to launching Endari® commercially in Oman and expanding its availability to other countries in the region."

Endari® is also approved for marketing in the United States, Israel, Bahrain, Kuwait, Qatar, and the United Arab Emirates and is available on a named patient or early access basis in France, The Netherlands, and the Kingdom of Saudi Arabia. Emmaus is pursuing additional regulatory approvals for Endari® in other countries where sickle cell disease is prevalent.

<sup>1</sup>Source: [Sickle cell disease in Oman and HBS Oman: a brief review]

## (https://medcraveonline.com/HTIJ/HTIJ-04-00100.pdf)

#### **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 <a href="https://www.emmausmedical.com">www.emmausmedical.com</a>.

## **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. 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. 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 Qatar 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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