

January 29, 2025



# Emmaus Life Science Reports Grant of Endari Market Exclusivity In Kingdom of Saudi Arabia

**Initial One-Year Exclusivity Period Will Be Extended to Three Years if Endari is Approved for Marketing**

TORRANCE, Calif., Jan. 29, 2025 /PRNewswire/ -- **Emmaus Life Sciences, Inc.** (OTCQB: EMMA), a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease, announced today that its Endari® (L-glutamine oral powder) has been afforded market exclusivity in the Kingdom of Saudi Arabia, or KSA, by the National Uniform Procurement Agency, or NUPCO (NUPCO Tender No. 014/24 COMPLIMENTARY PHARMA TENDER January 09, 2025). NUPCO, KSA's unified purchasing system, extends to all KSA government institutions, including hospitals under the Ministry of Health, Military Hospitals, the National Guard, the Security Forces, and King Faisal Specialty Hospitals and Research Centers.



"We are honored and pleased that NUPCO has selected Endari as the exclusive L-glutamine prescription therapy to treat sickle cell disease in the large addressable market of affected patients in KSA's healthcare system," commented Willis Lee, Chairman and Chief Executive Officer of Emmaus.

"While the exclusivity period will be for an initial period of one, we are informed that it will be extended for an additional two years if our pending marketing registration for Endari is approved in the KSA," added Charles W. Stark, Pharm. D., Executive Vice President and Chief Scientific Officer.

## **About Emmaus Life Sciences**

Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease. Endari® (L-glutamine oral powder), indicated to reduce the acute complications of sickle cell disease in adults and children 5 years and older, is approved for marketing in the United States, Israel, Kuwait, Qatar, the United Arab Emirates, Bahrain and Oman and is available on a named patient or early access basis in

France, the Netherlands, and the Kingdom of Saudi Arabia, where Emmaus' application for marketing authorization is awaiting final action by the Saudi Food & Drug Authority. 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 U.S. Food and Drug Administration (FDA) in July 2017 for treating sickle cell disease in adult and pediatric patients five years of age and older.

**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 the possibility of marketing approval for Endari in the KSA. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including the company's need to restructure or refinance its existing

indebtedness and raise additional funds from related-party loans, third-party loans or other financing to meet its current liabilities and fund its business and operations and doubt about the company's ability to continue as a going concern and other factors disclosed in the company's Annual Report on Form 10-K for the year ended December 31, 2023 and Quarterly Reports on Form 10-Q for the quarter ended September 30, 2024, 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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