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Emmaus Life Sciences Receives FDA Approval for Endari® Label Enhancements

Changes Based on Additional Pharmacokinetics Data

TORRANCE, Calif., June 26, 2025 /PRNewswire/ -- **Emmaus Life Sciences, Inc.** (OTCQB: EMMA), a leader in sickle cell disease treatment, announced today that it has received Food and Drug Administration (FDA) approval for changes to the labelling of Endari® to reflect additional prescribing information derived from post-marketing pharmacokinetic study data submitted by Emmaus. The additional information provides a more comprehensive characterization of Endari, including confirmation of dosing by body weight, no unwanted accumulation through twice daily dosing, and the ability to administer Endari with or without food. 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.

About Emmaus Life Sciences

Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company focused on the discovery, development, marketing, and sale of innovative treatments and therapies, including those for rare and orphan diseases. 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 aged five years 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 safety of Endari. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including the risks 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.

Company Contact:
Emmaus Life Sciences, Inc.
Investor Relations
IR@emmauslifesciences.com

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