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Emmaus Life Sciences Announces Support of Sickle Cell Disease Legislation

Bill Aims to Improve Understanding of Health Care System Utilization for Patients with SCD

TORRANCE, Calif. & NEW YORK--(BUSINESS WIRE)-- [Emmaus Life Sciences, Inc.](#) (Emmaus), today announced its support of the Sickle Cell Disease Surveillance, Prevention, and Treatment Act of 2018 ([S. 2465](#)). The legislation seeks to improve the understanding of health care system utilization patterns of people with sickle cell disease (SCD) and establish cost-effective practices to improve and extend the lives of these patients.

On July 25, the Senate Health, Education, Labor, and Pensions (HELP) Committee unanimously approved S. 2465, the Sickle Cell Disease Research, Surveillance, Prevention and Treatment Act of 2018. Next, it will be reviewed by the full Senate.

Sickle cell disease is an inherited blood disorder characterized by the production of an altered form of hemoglobin which polymerizes and becomes fibrous, causing red blood cells to become rigid and change form so they appear sickle shaped instead of soft and rounded. Patients with sickle cell disease suffer from debilitating episodes of sickle cell crises, which occur when the rigid, adhesive and inflexible red blood cells occlude blood vessels. Sickle cell crises cause excruciating pain as a result of insufficient oxygen being delivered to tissue, referred to as tissue ischemia, and inflammation. These events may lead to a variety of other adverse outcomes such as acute chest syndrome that requires hospitalization. Sickle cell disease is an orphan disease, affecting approximately 100,000 patients in the U.S. and millions worldwide, with significant unmet medical needs.

"As a physician who has treated SCD patients for more than twenty years, I know first-hand the impact of this disease," said Yutaka Niihara, MD, MPH, CEO and founder of Emmaus Life Sciences. "This condition exacts a terrible toll on patients, their families and the community in terms of pain, missing school or work and hospitalizations. We are pleased to see this legislation and look forward to it being passed."

Juanita Gougis added, "As a patient with sickle cell disease, I am adding my voice in support of this bill and its recognition of the importance of a better understanding of the prevalence of SCD and its associated health implications."

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Endari™ (L-glutamine oral powder), Emmaus' first commercially available product, was approved in July 2017 by the FDA and was the first treatment in nearly 20 years for sickle cell disease. Endari has received Orphan Drug designation in the U.S., and Orphan Medicinal Product designation in the EU.

On July 18, 2018, Emmaus [announced](#) that the [New England Journal of Medicine](#) published results of the company's 48-week, phase 3 clinical trial of Endari, which supported the FDA approval in July 2017.

About Endari™

Indication

Endari is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

Important Safety Information

The most common adverse reactions (incidence >10%) in clinical studies were constipation, nausea, headache, abdominal pain, cough, pain in extremity, back pain, and chest pain.

Adverse reactions leading to treatment discontinuation included 1 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 5 years of age has not been established.

For more information, please see full Prescribing Information of Endari at www.ENDARlrx.com/PI.

About Emmaus Life Sciences, Inc.

Emmaus Life Sciences, Inc. is a biopharmaceutical company engaged in the discovery, development and commercialization of innovative treatments and therapies primarily for rare and orphan diseases. Its lead product, Endari, demonstrated positive clinical results in the completed Phase 3 clinical trial for sickle cell anemia and sickle β 0-thalassemia and has received FDA approval. Visit: <http://www.emmausmedical.com/>.

Forward-Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, regarding the research, development and potential commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. Additional risks and uncertainties are described in reports filed by Emmaus Life Sciences, Inc., with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. Emmaus is providing this information as of the date of this press release and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

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