

April 18, 2017



## **Emmaus Life Sciences Inc. Announces FDA Advisory Committee Meeting for Endari™ for Sickle Cell Disease**

TORRANCE, Calif., April 18, 2017 /PRNewswire/ -- Emmaus Life Sciences Inc. announced today that the Oncologic Drug Advisory Committee of the U.S. Food and Drug Administration (FDA) has set a date of May 24, 2017 to review the Company's New Drug Application (NDA) for its orally-administered pharmaceutical grade L-glutamine product (Endari™), for the treatment of sickle cell disease.

"The Advisory Committee meeting is an important step forward in the review process for this promising therapy," said Yutaka Niihara, MD, MPH, Chairman and Chief Executive Officer of Emmaus Life Sciences. "We look forward to engaging in a productive discussion with the Advisory Committee members and continuing to work closely with the FDA throughout the regulatory process."

If approved, Endari would be the first FDA-approved treatment for pediatric patients with sickle cell disease, and the first new treatment in nearly 20 years for adult patients. Endari has received Orphan Drug designation in the U.S., Orphan Medicinal Product designation in the EU and Fast Track designation from the FDA.

The Company's NDA for Endari was accepted for review by the FDA in early November 2016 with a target action date under the Prescription Drug User Fee Act set for July 7, 2017.

### **About Sickle Cell Disease**

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 that 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 organ damage, stroke, pulmonary complications, skin ulceration, infection and a variety of other adverse outcomes. Sickle cell disease is an orphan disease, affecting approximately 100,000 patients in the U.S. and millions worldwide with significant unmet medical needs.

### **About Emmaus Life Sciences**

Emmaus Life Sciences is engaged in the discovery, development and commercialization of innovative treatments and therapies for rare diseases. The company's research on sickle cell disease was initiated by Yutaka Niihara, MD, MPH, Chairman and CEO of Emmaus, at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. For more

information, please visit [www.emmauslifesciences.com](http://www.emmauslifesciences.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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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/emmaus-life-sciences-inc-announces-fda-advisory-committee-meeting-for-endari-for-sickle-cell-disease-300440161.html>

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