

November 29, 2016



Emmaus Life Sciences Receives Notice of FDA PDUFA Date for Investigational L-glutamine Treatment for Sickle Cell Disease

Company to Present Subgroup Data Analysis from Phase 3 Trial at the American Society of Hematology meeting

TORRANCE, Calif., Nov. 29, 2016 /PRNewswire/ -- Emmaus Life Sciences, Inc. announced today that the U.S. Food and Drug Administration has set a PDUFA date of July 7, 2017 for a decision on the Company's New Drug Application for its orally-administered pharmaceutical grade L-glutamine (PGLG) product for the treatment for sickle cell disease. The company also announced it will present data from a subgroup analysis of its Phase 3 clinical trial with PGLG treatment at the 58th American Society of Hematology Annual Meeting & Exposition in San Diego, CA.

"Notification of the PDUFA date brings us one step closer to providing healthcare providers and patients with a new treatment option for sickle cell disease," said *Yutaka Niihara, MD, MPH, Chairman and* Chief Executive Officer of Emmaus Life Sciences. "There is a scarcity of therapies for this debilitating condition and we look forward to working closely with the agency over the coming months as it reviews our new drug application."

If approved by the FDA, PGLG could 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. Emmaus' PGLG therapy has received Orphan Drug designation in the U.S., Orphan Medicinal Product designation in the EU and Fast Track designation from the FDA. Emmaus also plans to submit a marketing authorization application to the European Medicines Agency.

Poster Presentation at ASH Annual Meeting

Title: ***Phase 3 Study of L-Glutamine Therapy in Sickle Cell Anemia and Sickle β -Thalassemia Subgroup Analyses Show Consistent Clinical Improvement*** (Abstract #1318)

Session Name: 114. Hemoglobinopathies, Excluding Thalassemia—Clinical: Poster I

Session Date: Saturday, December 3, 2016

Session Time: 5:30–7:30 PM PT

The poster presents data on the rate of sickle cell crises (SCCs) with PGLG treatment vs. placebo over a 48-week period within the patient subgroups of age (age 5 to 18 years, and

age >18 years), gender and hydroxyurea use (specifically patients who received hydroxyurea treatment before and during the trial, and patients who did not). Consistent clinical improvement was seen in all subgroups.

The company previously reported data from its Phase 3 sickle cell disease trial, which demonstrated a reduction in the frequency of SCCs and hospitalizations, as well as a reduction in cumulative days hospitalized, and a lower incidence of the life-threatening acute chest syndrome. The clinical trial enrolled 230 adult and pediatric patients as young as five years old, across 31 experienced sickle cell disease treatment centers in the U.S. No major adverse events were attributable to the treatment.

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, M.D., 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.

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.

For more information, contact:

Media:
Jim Heins
Senior Vice President
ICR Healthcare
203-682-8251

Investors:
Charles Butler
Senior Vice President
ICR Healthcare
415-430-2079

james.heins@icrinc.com

charles.butler@icrinc.com

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/emmaus-life-sciences-receives-notice-of-fda-pdufa-date-for-investigational-l-glutamine-treatment-for-sickle-cell-disease-300369546.html>

SOURCE Emmaus Life Sciences, Inc.