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Emmaus' New Drug Application for Sickle Cell Disease Accepted for Review by FDA

TORRANCE, Calif., Nov. 8, 2016 /PRNewswire/ -- Emmaus Life Sciences, Inc., announced today that the Food and Drug Administration (FDA) has accepted for review the New Drug Application for its orally administered pharmaceutical grade L-glutamine (PGLG) treatment for sickle cell disease.

Data from the company's Phase 3 sickle cell disease trial demonstrated a reduction in the frequency of sickle cell crises 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. If approved, this represents the first potential treatment for pediatric patients with sickle cell disease, and the first potential new treatment in nearly 20 years for adult patients.

The company is awaiting notice from the FDA regarding its request for a priority review. Emmaus' sickle cell disease therapy has 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.

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 crisis, which occur when the rigid, adhesive and inflexible red blood cells occlude blood vessels. Sickle cell crisis causes 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 in the U.S., 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:
Roger Pondel/Judy Sfetcu
PondelWilkinson Inc.
310-279-5980
rpondel@pondel.com
jsfetcu@pondel.com

Media:
Lori Teranishi
510-290-6160
lteranishi@iq360inc.com

Investors:
Willis Lee
310-214-0065
wlee@emmauslifesciences.com