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Emmaus Life Sciences to Seek Marketing Approval for First New Sickle Cell Disease Treatment in Nearly 20 Years; Expects to Submit New Drug Application to FDA in September

NDA Submission Coincides with National Sickle Cell Disease Awareness Month

TORRANCE, Calif., Aug. 22, 2016 /PRNewswire/ -- Culminating more than 20 years of research and development, Emmaus Life Sciences, Inc. today announced that it expects to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in September for the company's treatment for sickle cell disease. Sickle cell disease is one of the most devastating hereditary disease with painful symptoms and shortened life span. The treatment consists of orally administered pharmaceutical grade L-glutamine.

The submission, expected in early September, coincides with National Sickle Cell Disease Awareness Month, which calls attention to sickle cell disease, which, according to the National Institutes of Health, is estimated to affect as many as 100,000 Americans and 25 million people worldwide.

"The submission of the NDA is the culmination of many people's life work, marking a milestone for all the patients, researchers, investors, partners, advocates and employees who have contributed to this achievement," said Yutaka Niihara, M.D., MPH, Chairman and CEO of Emmaus. "We look forward to the NDA submission early next month and discussing the positive safety and efficacy data from the trial with the FDA."

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 of age, across 31 experienced sickle cell disease treatment centers in the United States. There were no major adverse events attributable to the treatment.

Emmaus' sickle cell disease therapy has Orphan Drug designation in the U.S. and Europe and Fast Track designation from the FDA.

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 Dr. Niihara 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.

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