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Emmaus Life Sciences Announces FDA Acceptance of IND Application for Clinical Study of L-glutamine for Treatment of Diverticulosis

TORRANCE, Calif.--(BUSINESS WIRE)-- Emmaus Life Sciences (Emmaus), a biopharmaceutical company based in Torrance, California, today announced that the U.S. Food and Drug Administration has accepted its Investigational New Drug (IND) application for L-glutamine as a treatment for diverticulosis. FDA's acceptance of the IND clears the way for commencement of Emmaus' pilot study to assess the safety and efficacy of L-glutamine oral powder for treating diverticulosis. Emmaus expects to begin the study by the end of 2018.

The interventional, open-label, single-center pilot study will investigate the safety, tolerability and efficacy of L-glutamine treatment in approximately five to 10 patients with uncomplicated, asymptomatic diverticulosis over a period of 12 months.

"We're grateful for the opportunity to move forward with studying the effects of L-glutamine for the treatment of diverticulosis, a common condition affecting millions of people in the U.S. alone," said Yutaka Niihara, MD, MPH, Chairman and CEO of Emmaus Life Sciences. "The FDA's acceptance of our IND application represents an important milestone as we look to help improve the well-being of those afflicted by this common condition."

Approximately 40 percent of people over the age of 60 have diverticulosis, in which small pouches called diverticula develop in the wall or lining of the digestive tract. Ten to 25 percent of patients with diverticulosis develop diverticulitis, in which the pouches become inflamed or infected and can require hospitalization and surgery.

Patents have been issued for the use of L-glutamine in the treatment of diverticulosis in the U.S., Japan, Australia, China, Mexico, Indonesia, South Korea and Russia. Related patent applications are currently pending in Europe, Brazil and India.

About Emmaus Life Sciences

Emmaus Life Sciences, Inc. 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.

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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