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Emmaus Life Sciences Announces Positive Top-Line Results Of Its Phase 3 Clinical Trial For Sickle Cell Disease

TORRANCE, Calif., March 19, 2014 /PRNewswire/ -- Emmaus Life Sciences, Inc. (the "Company," or "Emmaus"), a biopharmaceutical company dedicated primarily to the discovery, development and commercialization of innovative treatments and therapies for rare and orphan diseases, today announced that preliminary top-line results of its Phase 3 clinical trial evaluating the safety and efficacy of its treatment for sickle cell anemia and sickle beta-0 thalassemia met both the primary and secondary endpoints of the clinical trial.

The prospective, randomized, double-blind, placebo-controlled, parallel-group, multi-center clinical trial enrolled 230 adult and pediatric patients as young as five years of age, across 31 U.S. sites. For the primary endpoint, top-line data based on an initial analysis revealed a statistically significant 25 percent reduction in the median frequency of sickle cell crises ($p=0.008$) over a 48-week time period. For the secondary endpoint, top-line data based on an initial analysis also showed a statistically significant 33 percent reduction in the median frequency of hospitalizations ($p=0.018$) over a 48-week time period. Both adult and pediatric patients receiving treatment demonstrated improvement. Furthermore, the therapy demonstrated a well-tolerated safety profile.

"We are very pleased with the strength of our Phase 3 data with respect to the primary and secondary endpoints. We intend to submit a New Drug Application to the FDA in mid-2014 for marketing approval of this treatment for sickle cell disease patients," said Dr. Yutaka Niihara, M.D., M.P.H., founder and CEO of Emmaus Life Sciences. "I particularly want to acknowledge the patients and medical centers whose participation made this clinical trial possible and the support of our investors who helped us achieve this significant milestone."

The Company's research on sickle cell disease and sickle beta-0 thalassemia was initiated by Dr. Niihara at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. The therapy has Orphan Drug designation in the U.S. and Europe and Fast Track designation from the FDA. Further results from the clinical trial will be released when available and are expected to be presented at a scientific meeting later this year.

About Sickle Cell Disease

Sickle cell disease is an inherited blood disorder causing red blood cells to become oxidized, forming rigid and sickled shaped cells that block small blood vessels. The condition causes debilitating pain crises and organ damage that can lead to death at an early age. Sickle cell disease affects approximately 100,000 people in the United States, an estimated 80,000 people in the European Union, and 20-25 million people worldwide. The disease particularly

occurs among those whose ancestors are from regions including sub-Saharan Africa, South America, the Caribbean, Central America, the Middle East, India and the Mediterranean.

About the Clinical Trial Design

The prospective, randomized, double-blind, placebo-controlled, parallel-group, multi-center clinical trial, primary outcomes measured the number of occurrences of protocol-defined sickle cell crises that occur from Week 0 to Week 48. Secondary outcomes included measuring the number of sickle cell crises over 24 weeks; the number of hospitalizations for sickle cell pain at 24 and 48 weeks; the number of emergency room/medical facility visits for sickle cell pain at 24 and 48 weeks; change from baseline (Week 0) for hemoglobin, hematocrit, and reticulocyte count at 24 and 48 weeks; all adverse events that occurred between baseline (Week 0) and the completion of the clinical trial; and laboratory parameters and vital signs, with complete blood count (CBC) and reticulocyte count collected at screening, baseline, and weeks 4, 8, 12, 16, 20, 24, 32, 40, 48, and 53.

The clinical trial enrolled 230 patients at least five years of age that had been diagnosed with sickle cell anemia or sickle beta-0 thalassemia and had at least two documented episodes of sickle cell crisis within 12 months of the screening visit. If the patient had been treated with an anti-sickling agent within three months of the screening visit, the therapy must have been continuous for at least three months with the intent to continue for the duration of the clinical trial.

About Emmaus Life Sciences

Emmaus is dedicated to the discovery, development and commercialization of innovative and therapies for rare diseases.

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 for the year ended December 31, 2012 and Quarterly Reports on Form 10-Q for the periods ended March 31, 2013, June 30, 2013 and September 30, 2013. 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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