December 21, 2017

Emmaus Life Sciences Sickle Cell Treatment Receives Positive Opinion on Pediatric Investigation Plan from European Medicines Agency

TORRANCE, Calif.--(BUSINESS WIRE)-- Emmaus Life Sciences announced today that the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) has accepted the company's pediatric investigation plan (PIP) for its treatment of sickle cell disease. The decision allows Emmaus to proceed with the submission of a Marketing Authorization Application (MAA).

“The approval of our PIP represents a significant step forward in our efforts to bring this treatment to market in the European Union (EU),” said Yutaka Niihara, MD, MPH, Chairman and Chief Executive Officer of Emmaus Life Sciences, “We look forward to submitting our MAA in the near term and hope to provide sickle cell patients in the EU with a new treatment option once we complete the regulatory process.”

The EMA requires companies seeking to register new medicines to agree with the PDCO on a PIP that outlines a clinical development program for studying the investigational product in the pediatric population. An accepted PIP is required before a company can file an MAA for a new drug in the EU.

On July 7, 2017, the United States (U.S.) Food and Drug Administration approved Endari™ (L-glutamine oral powder), for its use in the U.S.

Emmaus has obtained both Orphan Drug designation in the U.S. and Orphan Medicinal Product designation in the E.U.

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 a variety of other adverse outcomes such as acute chest syndrome that requires hospitalization. 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 Endari™

Indication

Endari is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

Important Safety Information

The most common adverse reactions (incidence >10%) in clinical studies were constipation, nausea, headache, abdominal pain, cough, pain in extremity, back pain, and chest pain.

Adverse reactions leading to treatment discontinuation included 1 case each of hypersplenism, abdominal pain, dyspepsia, burning sensation, and hot flash.

The safety and efficacy of Endari in pediatric patients with sickle cell disease younger than 5 years of age has not been established.

For more information, please see full Prescribing Information of Endari at www.ENDARIrx.com/Repository/Prescribing%20information.pdf

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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Source: Emmaus Life Sciences