March 12, 2018

Emmaus Life Sciences Receives Validation From European Medicines Agency on Marketing Authorization Application for Sickle Cell Disease Treatment Xyndari (oral glutamine)

TORRANCE, Calif.--(BUSINESS WIRE)-- Emmaus Life Sciences, Inc. (Emmaus) announced today that the company's Marketing Authorization Application (MAA) for Xyndari has been fully validated and is now under assessment by the European Medicines Agency (EMA) for the treatment of sickle cell disease.

"Sickle cell disease patients in the European Union have not had access to new therapies for almost 20 years," said Yutaka Niihara, MD, MPH, CEO and chairman of Emmaus. "The submission of this application reflects our continued commitment to provide treatment options for this painful and life-threatening disease to as many patients as possible."

The MAA is supported by data from the company's phase 3 randomized, double-blind, placebo-controlled, multi-center clinical trial of 230 patients ages 5 to 58 years old with sickle cell disease who had two or more painful crises within 12 months prior to enrollment. Patients who were treated with Xyndari over a 48-week period experienced fewer crisis episodes compared to patients who received a placebo (median 3 vs. median 4), fewer hospitalizations for sickle cell pain (median 2 vs. median 3), and fewer days in the hospital (median 6.5 days vs. median 11 days). Study patients on Xyndari also had fewer occurrences of acute chest syndrome, a life-threatening complication of sickle cell disease (8.6 percent vs. 23.1 percent). A sickle cell crisis was defined as a visit to an emergency room/medical facility for sickle cell disease-related pain treated with a parenterally administered narcotic or ketorolac; the occurrence of chest syndrome, priapism, and splenic sequestration were also considered sickle cell crises. The most common adverse reactions (incidence >10 percent) in clinical studies were constipation, nausea, headache, abdominal pain, cough, pain in extremity, back pain and chest pain.

Xyndari for the treatment of sickle cell disease will be reviewed by the EMA under the centralized licensing procedure for all 28 member states of the European Union, Norway and Iceland. Xyndari has also received orphan designation and an approved paediatric investigation plan (PIP) from the EMA.

Outside the United States, this treatment is currently available through an early access program based on a named patient use for sickle cell disease patients that have exhausted other treatment options. This program is administered by myTomorrows and provides

physicians in the EU, Turkey, Middle East and South America with the possibility to prescribe oral L-glutamine to eligible patients prior to marketing authorization.

The U.S. Food and Drug Administration (FDA) approved Endari™ (L-glutamine oral powder) for the treatment of sickle cell disease, specifically to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older, on July 7, 2017. Endari is currently available by prescription to patients with sickle cell disease in the U.S.

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 five years of age and older.

Important Safety Information

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

Adverse reactions leading to treatment discontinuation included one 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 five 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 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.

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Source: Emmaus Life Sciences, Inc.