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Emmaus Life Sciences Announces Withdrawal of Marketing Authorization Application to European Medicines Agency

TORRANCE, Calif., Sept. 19, 2019 /PRNewswire/ --**Emmaus Life Sciences, Inc.** (OTC: EMMA), a leader in sickle cell disease treatment, today announced the withdrawal of its marketing authorization application (MAA) to the European Medicines Agency (EMA) for Xyndari™ (glutamine) for the treatment of sickle cell disease.

Xyndari was approved under the tradename Endari® (L-glutamine oral powder) by the FDA to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older, based on the results of a Phase 3 study and other supportive studies. Despite the results of the Phase 3 study and other data submitted to the EMA's Committee for Medicinal Products for Human Use (CHMP), the CHMP maintains its initial opinion that the MAA did not demonstrate that Xyndari is effective at reducing the number of sickle cell disease crises or hospital visits.

"Because we have demonstrated the efficacy of Xyndari, as supported by the data from the trials conducted, we are disappointed in the CHMP's position," said Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus. "We remain committed to the patients who suffer from sickle cell disease and will continue to endeavor to broaden our global patient base, while identifying new clinical uses for L-glutamine, obtaining additional patents and distribution partners, and through ongoing community and physician outreach. We are seriously considering a decentralized approval procedure on a country by country basis."

Outside the United States, Xyndari is currently supplied through early access programs based on named patient use in a number of EU member states, Turkey and the Middle East. Xyndari received orphan designation by the European Commission in 2012 for the treatment of sickle cell disease and has also received an approved pediatric investigation plan (PIP) from the EMA.

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 organ damage, stroke, pulmonary complications, skin ulceration, infection and a variety of other adverse outcomes. Sickle cell disease is a significant unmet medical need, affecting approximately one hundred thousand patients in the U.S. and millions worldwide, the majority of which are of African descent. An estimated 1-in-365 African-American children is born with sickle cell disease.

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 in clinical studies include constipation, nausea, headache, and abdominal 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: http://www.ENDARIrx.com/PI.

About Emmaus Life Sciences

Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company engaged in the discovery, development, marketing and sale of innovative treatments and therapies, including those in the rare and orphan disease categories. For more information, please visit www.emmauslifesciences.com.

Forward-looking Statements

Except for the historical information contained herein, the matters discussed in this press release are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time. Forward-looking statements speak only as of the date they are made, and Emmaus assumes no duty to update forward-looking statements. Factors previously disclosed in Emmaus' reports filed with the Securities and Exchange Commission, among others, could cause actual results to differ materially from forward-looking statements.

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