July 29, 2020

Emmaus Life Sciences Receives Scientific Advice From the EMA Regarding Xyndari™

TORRANCE Calif., July 29, 2020 (GLOBE NEWSWIRE) -- **Emmaus Life Sciences, Inc. (OTCQB: EMMA)**, a leader in sickle cell disease treatment, announced today that the European Medicines Agency (EMA) issued scientific advice to Emmaus regarding the clinical development pathway for Xyndari™ for the treatment of sickle cell disease. Xyndari™ is the European brand name for the same Emmaus prescription product, Endari®, approved by the FDA and Israeli Ministry of Health.

The thoughtful and thorough feedback received during productive discussions with the Scientific Advice Working Party (SAWP) and the final written advice it received from the Committee for Medicinal Products for Human Use (CHMP) is greatly appreciated by Emmaus and will be very constructive in pursuing EMA approval for Xyndari™. Data from the FDA post-marketing commitment studies for Endari® will be presented to the SAWP when it becomes available. The EMA feedback regarding the emerging science and novel clinical study designs in the field of sickle cell disease drug development will assist Emmaus in optimizing the clinical studies for a future European Union (EU) marketing authorization application for Xyndari™.

Endari® is currently available to sickle cell disease patients in Europe on an early access basis only. It currently has a ten-year orphan drug designation (plus a two-year pediatric investigation plan) in the EU.

Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus, stated, “We are committed to the development and improvement in the treatment of sickle cell disease worldwide. As such, our goal is to bring Endari® and Xyndari™ to those who are in need as soon as possible.” Dr. Niihara commented further, “Emmaus is very appreciative of the guidance provided by the CHMP that will bring further credibility to the efficacy and safety of Xyndari™. We are also very grateful for the continued support of the FDA as Emmaus works on its post marketing commitment studies.”

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.emmausmedical.com.

About Endari® (L-glutamine oral powder)
Indication (U.S.) - 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/PI.

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 are born with sickle cell disease.

Forward-looking Statements
This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding the potential path forward for marketing authorization for Xyndari™ in the EU and possible outcome of FDA post-marketing studies of Endari®. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including risks and uncertainties inherent in human drug development, the availability of working capital and Emmaus' ability to carry on its existing operations and obtain needed financing and other factors previously disclosed in the company's reports filed with the Securities and Exchange Commission, and actual results may differ materially. Such forward-looking statements speak only as of the date they are made, and Emmaus assumes no duty to update them, except as may be required by law.

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Source: Emmaus Life Sciences