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Emmaus Life Sciences Announces Submission of Marketing Authorization Application to Swissmedic Ideogen, A.G. to Manage Early Access Program

TORRANCE, Calif., June 15, 2021 /PRNewswire/ -- **Emmaus Life Sciences, Inc.** (OTC: EMMA), a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease, announced today it has received confirmation from the Swiss Agency for Therapeutic Products (Swissmedic) of Emmaus' application for Marketing Authorization (MA) for Endari® in Switzerland. Swissmedic is responsible for the authorization and supervision of therapeutic products in Switzerland. In November 2020, Swissmedic granted Endari® orphan drug status.



Swissmedic's MA review and approval process typically takes 16 to 18 months. Endari® will be available to sickle cell disease patients on an early-access basis during the review and approval process. According to the University of Zurich, there were an estimated 220 people with sickle cell disease in Switzerland in 2017 and that number is expected to increase. Endari®, Emmaus' prescription grade L-glutamine oral powder, is approved by the United States FDA and the Israeli Ministry of Health to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older.

"We are looking forward to Swissmedic's review of our MA application for Endari®, which represents another important step in our progress and commitment to reach and improve the lives of sickle cell disease patients internationally," said Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus. "We will present for Swissmedic's review our study data that led to FDA approval of Endari® along with additional data and patient experience acquired since the approval."

George Sekulich, Senior Vice President of Global Commercialization of Emmaus, added, "With the Swissmedic marketing authorization approval process underway, we continue building and enhancing Emmaus' relationships with hematologists and patient advocacy groups in Switzerland to afford sickle cell disease patients access to Endari® in the most

expeditious and efficient manner possible."

Murat Goker, Head of Europe of Ideogen A.G., further commented, "Sickle cell disease is an orphan disease and chronic illness with debilitating symptoms affecting the lives of 250 to 300 patients in Switzerland. The limited approved treatment options in Switzerland classify sickle cell disease as an essential unmet medical need. Ideogen has partnered up with Emmaus to initiate a managed access program and register the drug Endari to improve access to an essential therapeutic option for physicians and patients alike."

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 Ideogen A.G.

Ideogen A.G. is a Swiss pharmaceutical group with a primary focus on specialty medicines for unmet medical needs. Ideogen strives to improve patients' quality of life and physicians' access to therapeutic options via managed access programs and approved marketing authorizations in the European continent. For more information, please visit www.ideogen.com.

About Endari® (prescription grade L-glutamine oral powder)

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.ENDARlrx.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 potential patient access to Endari®. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including uncertainties relating to possible future marketing approval in Switzerland 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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