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# Endari® Granted Orphan Drug Status in Switzerland

TORRANCE Calif., Dec. 3, 2020 /PRNewswire/ --**Emmaus Life Sciences, Inc.** (OTC: EMMA), a leader in the treatment of sickle cell disease, announced today that the Swiss Agency for Therapeutic Products (Swissmedic) has granted orphan drug status to Endari®. Orphan drug status (ODS) is available to medicinal products that treat conditions affecting no more than 5 out of 10,000 people in Switzerland or that have been granted ODS or its equivalent in another country with comparable medicinal product controls. Endari® also enjoys Orphan Drug status and Orphan Medicinal status in the United States and the European Union (Xyndari™), respectively.

Emmaus is preparing an Endari® Marketing Authorization (MA) application for submission to Swissmedic. The 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 to address an unmet medical need in Switzerland during the review and approval process.

Endari®, Emmaus' prescription grade L-glutamine oral powder, was approved by the FDA in July 2017 for treating sickle cell disease in adult and pediatric patients five years of age and older. Sales of Endari® began in the United States in 2018. Endari® received marketing authorization from the Israeli Ministry of Health in June 2020 and is currently available to sickle cell disease patients on an early access basis in the European Union and Middle East.

"We are pleased to be granted orphan drug status for Endari from Swissmedic. It represents an important step in our progress and commitment to serve sickle cell disease patients internationally," said Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus.

George Sekulich, Senior Vice President of Global Commercialization of Emmaus added, "While proceeding with the marketing authorization approval process, we look forward to building and enhancing Emmaus' relationships with hematologists and patient advocacy groups in Switzerland to provide sickle cell disease patients with Endari."

**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®** (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.ENDARIrx.co/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 marketing exclusivity and prospective marketing authorization approval of Endari® in Switzerland. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including uncertainties related to the future sales of Endari® in Switzerland, Emmaus' working capital and ability to carry on its existing operations and obtain needed financing and up-listing of Emmaus' common stock 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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