January 29, 2018

Emmaus Life Sciences Announces Medicaid Coverage of Endari™ (L-glutamine oral powder) for Sickle Cell Disease in the United States

TORRANCE, Calif.--(BUSINESS WIRE)-- Emmaus Life Sciences announced today that it has a Medicaid Drug Rebate Agreement with the Centers for Medicare & Medicaid Services allowing coverage of Endari (L-glutamine oral powder) to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older. All states currently provide coverage for outpatient prescription drugs under such agreements to all eligible Medicaid enrollees within their state Medicaid programs.

Endari is the first new treatment approved by the FDA for pediatric patients five years of age and older with sickle cell disease, and the first new treatment approved by the FDA in nearly 20 years for adult patients.[1]

“This treatment is considered very important by many providers and patients because of its excellent safety profile and the evidence of effectiveness from the phase III study that showed a reduction in acute chest syndrome, decreased occurrence of sickle crises and decreased frequency of hospitalizations in the Endari group compared to the placebo group,” said Yutaka Niihara, MD, MPH, Chairman and CEO of Emmaus Life Sciences. “Having the Medicaid Drug Rebate Program in place will make Endari more accessible to patients who need it most.”

FDA’s approval of Endari is based on safety and effectiveness data from a 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 Endari 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 Endari 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.

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, Inc. 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, MD, MPH, Chairman and CEO of Emmaus, at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. For more information, please visit http://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.

Reference

1. https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm418232.htm

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http://www.businesswire.com/news/home/20180129005283/en/

for Emmaus Life Sciences
Lori Teranishi, 510-290-6160
lteranishi@iq360inc.com
For Endari prescription questions: 833-831-1166

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