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The U.S. Food & Drug Administration Approves Endari™ (L-glutamine oral powder), the First and Only Treatment for Sickle Cell Disease in Pediatric Patients and First in Nearly 20 Years for Adults

Endari has shown to decrease the number of sickle cell crises and hospitalizations in patients with sickle cell disease

TORRANCE, Calif., July 7, 2017 /PRNewswire/ -- Emmaus Life Sciences Inc. announced today that the U.S. Food and Drug Administration (FDA) approved Endari™ (L-glutamine oral powder) to reduce the severe complications of sickle cell disease (SCD) in adult and pediatric patients age 5 and older. Endari reduces oxidant damage to red blood cells by improving the redox potential of nicotinamide adenine dinucleotide (NAD), a coenzyme that has been identified as the primary regulator of oxidation.

"The approval of Endari is a significant milestone for the sickle cell patient community who has not had an advancement in treatment for nearly 20 years and which now, for the first time ever, has a treatment option for children," said Yutaka Niihara, MD, MPH, Chairman and Chief Executive Officer of Emmaus Life Sciences. "Endari reinforces our commitment to discovering innovative therapies that help to improve the lives of people with rare diseases. We thank the FDA for its prompt review and look forward to making treatment available to patients as early as this fourth quarter."

SCD is a rare, debilitating and lifelong hereditary blood disorder that affects approximately 100,000 patients in the U.S. and up to 25 million patients worldwide, the majority of which are of African descent as well as Latinos and other minority groups. Approximately one in every 365 African American children is born with SCD and children between the ages of 2 and 7 are 400 times more likely to suffer from stroke.

Caused by a genetic mutation in the beta-chain of hemoglobin that distorts red blood cells into crescent shapes, SCD lowers oxygen levels in the blood and has an extensive impact on morbidity, mortality and quality of life. Patients often suffer from debilitating episodes of sickle cell crises, which occur when the rigid, adhesive and inflexible red blood cells block the blood vessels, resulting in excruciating pain. Sickle cell crises can lead to organ damage, stroke, pulmonary complications, and other adverse outcomes, including acute chest syndrome (ACS), which may be potentially fatal and is the leading cause of death among people with SCD.

"A sickle cell crisis is the most common acute complication for patients and the number one cause of emergency room visits," said Wally Smith, MD, Florence Neal Cooper Smith Professor of Sickle Cell Disease, Division of General Internal Medicine, Virginia Commonwealth University. "Endari has clinically shown to reduce sickle cell crises and hospitalizations, representing a significant medical advancement for patients with limited therapeutic options that have many side effects."

FDA approval was supported by efficacy data from a 48-week randomized, double-blind, placebo-controlled, multicenter Phase 3 clinical trial evaluating the effects of Endari, prescription grade L-glutamine, as compared to placebo on 230 adults and children with SCD. The results demonstrated that Endari reduced the frequency of sickle cell crises by 25 percent and hospitalizations by 33 percent. Additional findings showed a decrease in cumulative hospital days by 41 percent and lower incidence of ACS by more than 60 percent.

Safety was based on data from 298 patients treated with L-glutamine and 111 patients treated with placebo in the Phase 2 and Phase 3 studies. Endari's safety profile was similar to placebo and well-tolerated in pediatric and adult patients. The most common adverse reactions occurring in greater than 10 percent of patients treated with Endari were constipation, nausea, headache, abdominal pain, cough, pain in extremity, back pain, and chest pain (non-cardiac).

About Emmaus Life Sciences
Emmaus Life Sciences 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 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/the-us-food--drug-administration-approves-endari-l-glutamine-oral-powder-the-first-and-only-treatment-for-sickle-cell-disease-in-pediatric-patients-and-first-in-nearly-20-years-for-adults-300484785.html

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