



European Commission Grants Orphan Medicinal Product Designation for Emmaus Medical's Sickle Cell Treatment

-Company Provides Update on Phase III U.S. FDA Clinical Trials for the Treatment of Sickle Cell Disease-

TORRANCE, Calif., July 17, 2012 -- Emmaus Medical, Inc., a specialty pharmaceutical and regenerative medicine technology company, and subsidiary of Emmaus Life Sciences, Inc., today announced that the European Commission (EC) has granted Orphan Medicinal Product designation for the company's investigational drug Levoglutamide (L-glutamine) for the treatment of sickle cell disease. The EC designation follows the recommendation of the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products announced in May.

Sickle cell disease affects approximately 2.5 in 10,000 people in the European Union, according to studies filed with EMA. However, in some European countries, the concentration of those suffering from sickle cell disease is higher as a result of demographics, migration and geographic mobility, surpassing genetic disorders such as hemophilia and cystic fibrosis, according to a [study](#) in the Hematology Journal.

"The positive decision by the European Commission paves the way for us to provide accessible treatment to people throughout Europe who suffer from this debilitating disease," said Yutaka Niihara, M.D., MPH, founder and CEO of Emmaus. "Throughout the world a new treatment option for sickle cell disease is urgently needed, and we are committed to bringing a treatment to market for this severely underserved patient population."

Emmaus said it currently is conducting a clinical trial that is in Phase III with the U.S. Food and Drug Administration (FDA) to study L-glutamine as a treatment for sickle cell disease. Research is being conducted at over 30 clinical trial sites around the country with over 175 people presently enrolled. The company anticipates total enrollment of more than 200 and aims to complete the trial in 2013.

"We are pleased to have received this important designation, which provides for marketing exclusivity in the region and further enhances our efforts to team with a strategic partner, both in Europe and in other key regions," added Henry McKinnell, Ph.D., Chairman of the Board of Emmaus Life Sciences, Inc. and former CEO of Pfizer, Inc.

The patent protected treatment, whose research was led by Dr. Niihara and investigators at the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, has both an orphan drug designation and fast track status in the United States.

For more information about the clinical trial, please visit the Emmaus Medical website at www.emmausmedical.com or www.clinicaltrials.gov (NCT01179217).

About Orphan Drug Status in the European Union

The EMA grants orphan drug status for products that can be used in the diagnosis, treatment, or prevention of life-threatening or chronically debilitating conditions with an incidence rate of no greater than 5 in 10,000 individuals in the European Union. Orphan status is conferred when either no satisfactory method of diagnosis, prevention or treatment of the authorized condition exists, or, if such a method does exist, the treatment must be of significant benefit to patients affected by the condition. Orphan status allows the company 10 years of marketing exclusivity in all EU member countries after approval, and other benefits during the development and regulatory review process including scientific assistance for study protocols, access to a centralized review process covering all EU member countries, and reduced or waived registration and marketing authorization application fees.

About Sickle Cell Disease

Sickle cell disease is an inherited blood disorder causing red blood cells to become oxidized, forming rigid and sickled shaped cells that block small blood vessels. The condition causes debilitating pain crises and organ damages that can lead to death at an early age. An estimated 200,000 people in the United States and the Europe Union, and four to five million people worldwide, primarily in Latin America and Africa, are afflicted. Currently, there is no universal cure for sickle cell disease.

About Emmaus Medical, Inc.

Founded in 2000, Emmaus Medical, Inc. is a specialty pharmaceutical company, and subsidiary of Emmaus Life Sciences, Inc., dedicated to the discovery, development and commercialization of innovative and cost-effective treatments and therapies for rare diseases. The company is completing its Phase III clinical trial for a treatment for sickle cell disease and has entered into a collaborative agreement for the research, development and commercialization of regenerative medicine technology products. For more information, please visit www.emmausmedical.com and www.nutrestore.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "expects," "plans," "believes," "intends," and similar words or phrases. These forward-looking statements include, without limitation, statements regarding completion of the Phase III clinical trial in 2013, the potential for the L-glutamine treatment for sickle cell disease, the timing, progress and anticipated results of the clinical development of the L-glutamine treatment for sickle cell disease, Emmaus' ability to fund the development of the L-glutamine treatment to completion, as well as Emmaus' plans and objectives. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Various important factors could cause actual results or events to differ materially from the forward-looking statements that we make. Such factors include, among others, risks that the results of clinical trials will not support our claims or beliefs concerning the effectiveness of the L-glutamine treatment or any of our other product candidates, our ability to finance the development of our product candidates, regulatory risks, including our ability to obtain FDA, European Commission and other regulatory approval for L-glutamine treatment for sickle-cell disease, our ability to commercialize our L-glutamine treatment for sickle cell disease, and our reliance on third party researchers and other collaborators. 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 for the year ended December 31, 2011. 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.

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