



Former FDA Official Tim Coté Joins Emmaus Medical as Regulatory Advisor

***--Emmaus in Process of Completing Phase 3 Study
For First Widely Available Treatment for Sickle Cell Disease--***

TORRANCE, Calif., May 9, 2013 –Timothy Coté, M.D., MPH, former director of the Office of Orphan Product Development of the U.S. Food and Drug Administration, has joined Emmaus Medical, Inc., a specialty pharmaceutical and regenerative medicine company, in an advisory capacity, the company announced today. Dr. Coté will advise Emmaus on the regulatory pathway for the company’s sickle cell disease treatment.

“Dr. Coté’s extensive regulatory knowledge and experience in rare diseases will be extremely beneficial as we move toward completion of our phase 3 clinical trial and into the analysis phase of the study,” said Yutaka Niihara, M.D., MPH, founder and CEO of Emmaus Medical. “We remain on track to complete the study this year and look forward to working closely with Dr. Coté as we reach this important milestone, both for our company and the sickle cell disease community.”

Dr. Coté is a leading national regulatory expert in orphan drug development. As a part of 22 years of federal service at the FDA, National Institutes of Health (NIH) and Centers for Disease Control (CDC), Dr. Coté served as the Director of the FDA Office of Orphan Products Development (OODP) from 2007 to 2011. The OODP is the FDA's primary interface with companies seeking orphan designation for drug and device products or seeking guidance in navigating FDA processes in reviewing orphan products. Dr. Coté was instrumental in implementing the Orphan Drug Act and personally signed more than 800 orphan drug designations in his time at the Agency.

Dr. Coté also has served as Senior Federal Advisor to the Director, District of Columbia Department of Health; Branch Chief, Therapeutics and Blood Safety, FDA Center for Biologics Evaluation and Research (CBER); and Medical Director, Cancer Statistics Branch, National Cancer Institute. In 2011 Dr. Coté was the Chief Medical Officer for the National Organization for Rare Disorders (NORD). Currently, he is the

Professor of Regulatory Practice at the Keck Graduate Institute in Claremont, California and principal of Coté Orphan Consulting.

“Finding a widely available treatment for sickle cell diseases is a clear priority and goes to the heart of the creation of Sickle Cell Disease Initiative, a program launched by the U.S. Department of Health and Human Services nearly two years ago,” Dr. Coté said. “I look forward to collaborating with Emmaus on potentially bringing forward this much needed treatment.”

Emmaus’ patent-protected treatment for Sickle Cell Anemia and β^0 -Thalassemia has Fast Track designation from the FDA, Orphan Drug designation in the United States and Orphan Medicinal Product designation in the European Union.

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 3 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 products. For more information, please visit www.emmausmedical.com.

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