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# Cempra Withdraws Solithromycin Marketing Authorization Application in Europe

## —Company plans to resubmit MAA with additional data, in alignment with FDA strategy—

CHAPEL HILL, N.C., March 28, 2017 (GLOBE NEWSWIRE) -- Cempra, Inc. (Nasdaq:CEMP), a clinical-stage pharmaceutical company focused on developing differentiated anti-infectives for the acute care and community settings to meet critical medical needs in the treatment of infectious diseases, today announced that the company has withdrawn its marketing authorization application (MAA) seeking European Medicines Agency (EMA) approval of oral capsule and intravenous formulations of solithromycin for the treatment of community-acquired pneumonia in adults.

Based on the Day 120 questions Cempra received from the EMA, the company believes additional data would be required. By withdrawing the MAA at this time, Cempra will conserve considerable financial resources, and it will allow the company to align its strategy to provide additional data to both the EMA and U.S. Food and Drug Administration (FDA) to support potential approval.

"Our goal is to make solithromycin available in the EU to address an important unmet medical need. We believe the most efficient path to approval is to withdraw the MAA at this time and to resubmit it with the additional data requested by the FDA," said David Zaccardelli, Pharm.D., acting chief executive officer of Cempra.

If approved, solithromycin would be the first new oral and IV antibiotic available in the EU in more than 15 years. According to the European Respiratory Society (ERS), more than 3,000,000 cases of community-acquired pneumonia are diagnosed each year in the EU, resulting in approximately 1,000,000 hospitalizations annually. The ERS notes that antibiotic resistance is one of the major threats undermining the treatment of respiratory infections.

**About Cempra, Inc.**

Cempra, Inc. is a clinical-stage pharmaceutical company focused on developing differentiated anti-infectives for the acute care and community settings to meet critical medical needs in the treatment of infectious diseases. Cempra's two lead product candidates are currently in advanced clinical development. Solithromycin has been evaluated in two phase 3 clinical trials for community-acquired bacterial pneumonia (CABP). Cempra is currently seeking approval for both intravenous and oral capsule formulations from the U.S. Food and Drug Administration. Solithromycin is licensed to strategic commercial partner Toyama Chemical Co., Ltd., a subsidiary of FUJIFILM Holdings Corporation, for certain exclusive rights in Japan. Cempra is contracted with BARDA for the development of solithromycin for pediatric use and has commenced enrollment in a global Phase 2/3 trial to evaluate the safety and efficacy of solithromycin versus standard of care antibiotics in children and adolescents from two months to 17 years of age. Solithromycin is also in development for uncomplicated urogenital urethritis caused by *Neisseria gonorrhoeae* or chlamydia. Fusidic acid is Cempra's second product candidate, which has completed a phase 3 trial comparing fusidic acid to linezolid in patients with acute bacterial skin and skin structure infections (ABSSSI). Cempra also has an ongoing exploratory study of fusidic acid for chronic oral treatment of refractory infections in bones and joints. Both products seek to address the need for new treatments targeting drug-resistant bacterial infections in the hospital and in the community. Cempra is also studying solithromycin for ophthalmic conditions and has synthesized novel macrolides for non-antibiotic uses such as the treatment of chronic inflammatory diseases, endocrine diseases and gastric motility disorders. Cempra was founded in 2006 and is headquartered in Chapel Hill, N.C. For additional information about Cempra please visit www.cempra.com.

***Please Note:*** *This press release contains forward-looking statements regarding future events. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: our ability to address the issues identified by the FDA in the complete response letter relating to our new drug applications for solithromycin for community acquired bacterial pneumonia; our anticipated capital expenditures and our estimates regarding our capital requirements, including the costs of addressing the complete response letter; our ability to obtain FDA and foreign regulatory approval of solithromycin as a treatment for community-acquired bacterial pneumonia; our and our strategic commercial partners' ability to obtain FDA and foreign regulatory approval of our product candidates; and results of our and our strategic commercial partners' pre-clinical studies and clinical trials, which are not predictive of results from subsequent clinical trials for any possible therapy. The reader is referred to the documents that we file from time to time with the Securities and Exchange Commission.*

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