December 29, 2016

Cempra Receives Complete Response Letter From FDA For Solithromycin NDAs

Management to host webcast and conference call today at 9:00 a.m. ET

CHAPEL HILL, N.C., Dec. 29, 2016 (GLOBE NEWSWIRE) -- Cempra, Inc. (Nasdaq:CEMP), a clinical-stage pharmaceutical company focused on developing antibiotics to meet critical medical needs in the treatment of bacterial infectious diseases, today announced that the company has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) relating to the company's new drug applications (NDAs) for oral and intravenous solithromycin for the treatment of community-acquired bacterial pneumonia (CABP) in adults.

The CRL states that the FDA cannot approve the NDAs in their present form and notes that additional clinical safety information and the satisfactory resolution of manufacturing facility inspection deficiencies are required before the NDAs may be approved.

The FDA did not request any further information on solithromycin efficacy for CABP in the CRL.

Based on their review of the NDAs, the CRL stated that the FDA determined the risk of hepatotoxicity had not been adequately characterized. The FDA noted the size of the safety database is limited to 920 patients who received solithromycin at the proposed dose and duration, and is too small to adequately characterize the nature and frequency of serious hepatic adverse effects.

To address this deficiency, the FDA is recommending a comparative study to evaluate the safety of solithromycin in patients with CABP. Specifically, the CRL recommends that Cempra consider a study of approximately 9,000 patients exposed to solithromycin to enable exclusion of serious drug induced liver injury (DILI) events occurring at a rate of approximately 1:3000 with a 95 percent probability.

The CRL noted that while the FDA reserves comment on the proposed labeling until the NDAs are otherwise adequate, even in the absence of a case of Hy's Law or of another form of serious DILI in future studies, labeling will need to include adequate information about the potential for hepatotoxicity, limiting use to patients who have limited therapeutic options and limitations regarding duration of therapy. A comprehensive plan for post-marketing safety assessment including an enhanced pharmacovigilance program would also be required.

The CRL also stated that during recent inspections of the Wockhardt Limited and Hospira, Inc. manufacturing facilities, the FDA field investigator conveyed deficiencies to representatives of the facilities. Satisfactory resolution of these deficiencies is required prior to approval. Details on these deficiencies were not provided in the CRL.

Cempra plans to request a meeting with the FDA as soon as possible to discuss the issues identified in the CRL, including the design of the recommended clinical safety study and the steps necessary to resolve the deficiencies noted at Wockhardt and Hospira. The company also plans to provide the FDA with an update on manufacturing progress at Uquifia, an alternate GMP manufacturing facility for solithromycin active pharmaceutical ingredient (API).

"As the rates of antibiotic resistance continue to rise, there is an unmet medical need for new antibiotics to treat patients with CABP and Cempra is committed to working with the FDA to achieve the approval of solithromycin as quickly as possible," said David Zaccardelli, Pharm.D. acting chief executive officer of Cempra.

"With more than $225 million of cash on hand, patent protection for solithromycin through 2032 and a pipeline that includes fusidic acid and other potential programs for solithromycin, including an ophthalmic formulation, we have flexibility to determine the best course forward for solithromycin and Cempra," Zaccardelli added.

Conference Call and Webcast
Cempra management will host a 30 minute webcast and conference call regarding this announcement at 9:00 a.m. ET today. The live call may be accessed by dialing 877-377-7553 for domestic callers and 253-237-1151 for international callers and using conference number: 46313141. A live webcast of the call will be available from the investor relations sections of the company website at www.cempra.com, and will be archived there for 30 days. A telephone replay of the call will be available by dialing 855-859-2056 for domestic callers, or 404-537-3406 for international callers, and entering the conference number: 46313141.

About Cempra, Inc.
Cempra, Inc. is a clinical-stage pharmaceutical company focused on developing antibiotics to meet critical medical needs in the treatment of bacterial infectious diseases. Cempra's two lead product candidates are currently in advanced clinical development. Solithromycin has been successfully 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 FDA and the EMA. Solithromycin is licensed to strategic commercial partner Toyama Chemical Co., Ltd., a subsidiary of FUJIFILM Holdings Corporation, for certain exclusive rights in Japan. Solithromycin is also in a Phase 3 clinical trial for uncomplicated urogenital urethritis caused by *Neisseria gonorrhoeae* or chlamydia. 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. Fusidic acid is Cempra's second product candidate, which has completed enrollment of an initial 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 has also 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 ability to obtain FDA and foreign regulatory approval of solithromycin as a treatment for community acquired bacterial pneumonia; the impact of the recently announced changes in senior management and our ability to retain and hire necessary employees and to staff our operations appropriately; our anticipated capital expenditures and our estimates regarding our capital requirements, including the costs of addressing the complete response letter; our dependence on the success of solithromycin and fusidic acid; our and out strategic commercial partners' ability to obtain FDA and foreign regulatory approval of our product candidates; the costs, sources of funds, enrollment, timing, regulatory review and results of our studies and clinical trials and those of our strategic commercial partners; results of our and our strategic commercial partners' pre-clinical studies and clinical trials are not predictive of results from subsequent clinical trials for any possible therapy; the unpredictability of the size of the markets for, and market acceptance of, any of our products, including solithromycin and fusidic acid; our ability to commercialize and launch, whether on our own or with a strategic partner, any product candidate that receives regulatory approval; our ability to produce and sell any approved products and the price we are able to realize for those products; our need to obtain additional funding and our ability to obtain future funding on acceptable terms; the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties; our ability to compete in our industry; innovation by our competitors; and our ability to stay abreast of and comply with new or modified laws and regulations that currently apply or become applicable to our business. The reader is referred to the documents that we file from time to time with the Securities and Exchange Commission.

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