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# Cempra Presents Data on Ophthalmic Solithromycin at ARVO

CHAPEL HILL, N.C., May 10, 2017 (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 the company is presenting two abstracts highlighting topical ophthalmic formulations of solithromycin in preclinical models of activity, tolerability and pharmacokinetics (PK) in the eye at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO) in Baltimore, MD.

In one study, several formulations of 1% solithromycin ophthalmic solution were developed and screened in preclinical models to assess tolerability, and to evaluate achievement of desired PK parameters for an ophthalmic solution. Researchers found solithromycin ophthalmic solution to achieve appropriate concentrations in ocular and periocular tissues, and to be well tolerated with no signs of ocular redness, discomfort or irritation.

Clinically relevant concentrations of solithromycin were measured in multiple areas of the eye after a single topical dose while systemic plasma concentrations remained very low, regardless of the evaluated formulation.

In the other study, researchers assessed the effect of solithromycin on meibomian gland epithelial cells. Meibomian glands, which are found in the eyelids, secrete the lipid layer that protects the ocular tear film from becoming dry. Meibomian gland dysfunction is an important cause of dry eye disease.

Researchers found that solithromycin induced a rapid and dose dependent increase in healthy secretions from human meibomian gland epithelial cells, in vitro. This response was seen more rapidly than a similar effect observed with azithromycin in the same cell culture system.

"It is possible that solithromycin, by acting directly on human meibomian gland epithelial cells, may serve as an important treatment for human meibomian gland dysfunction and its associated dry eye disease," said David Sullivan, M.D., senior scientist and Margaret S. Sinon scholar in ocular surface research at Schepens Eye Research Institute and associate professor of ophthalmology at Harvard Medical School.

"These supportive data on potential formulations for ophthalmic solithromycin and its additional potential activity in dry eye are important as we continue to progress ophthalmic solithromycin towards an IND," said David Oldach, M.D., chief medical officer of Cempra.

**About Cempra, Inc.**

Cempra, Inc. is a clinical-stage pharmaceutical company focused on developing differentiated anti-infectives for 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 CABP 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: results of our and our strategic commercial partners' preclinical studies and clinical trials are not predictive of results from subsequent clinical trials for any possible therapy; our ability to obtain FDA*

*and foreign regulatory approval of solithromycin as a treatment for community acquired bacterial pneumonia; our dependence on the success of solithromycin and fusidic acid; our and our 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; 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; 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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