December 5, 2016

Toyama Chemical (a Subsidiary of FUJIFILM Holdings Corporation) Begins Phase 3 Studies in Japan With Cempra's Solithromycin

CHAPEL HILL, N.C., Dec. 05, 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 Toyama Chemical Co., Ltd. (Toyama) a subsidiary of FUJIFILM Holdings Corporation, has begun Phase 3 clinical trials with solithromycin in Japan, the world's second largest antibiotic market, for patients with community-acquired bacterial pneumonia (CABP) and other respiratory infections.

Earlier this year, Toyama completed a Phase 2 multi-center, randomized, double-blinded study of 135 Japanese patients with mild to moderate CABP. Patients were randomized to either oral solithromycin or oral levofloxacin for five days. Overall safety and tolerability was similar in both treatment groups and all efficacy outcome measures favored solithromycin. These data, and the data from Cempra's studies, were reviewed by Japan's Pharmaceuticals and Medical Devices Agency (PMDA) before finalizing the Phase 3 study protocol.

Toyama owns exclusive rights to develop and commercialize solithromycin in Japan for respiratory tract infections and other indications in adults and pediatric patients.

In November 2016, Cempra announced it had received a $10 million milestone payment when Toyama decided to progress to Phase 3 studies. Cempra has received $40 million of upfront and milestone payments from Toyama and can earn an additional $30 million, for a total of $70 million, in payments from Toyama based on the achievement of certain objectives. If approved, Toyama would pay tiered royalties, adjusted based on sales, to Cempra following launch of solithromycin in Japan.

"We are excited and encouraged to see Toyama commencing their Phase 3 program and moving another step closer to the potential approval of solithromycin in Japan, where already high antibiotic resistance in pneumococcus strains and other CABP pathogens is rising, highlighting the urgent unmet medical need for new therapies," said Prabhavathi Fernandes, Ph.D., chief executive officer of Cempra.

"We are also pleased that the Toyama Phase 3 trial will be against levofloxacin as the comparator, which is the fluoroquinolone used most frequently in outpatient CABP treatment," Fernandes added.

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) and applications for approval for both intravenous and oral capsule formulations have been accepted for review by 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: 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; our and our strategic commercial partners' ability to obtain FDA and foreign regulatory approval of our product

candidates, including solithromycin; our dependence on the success of solithromycin and fusidic acid; 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 ability to retain and hire necessary employees and to staff our operations appropriately; our need to obtain additional funding and our ability to obtain future funding on acceptable terms; our anticipated capital expenditures and our estimates regarding our capital requirements; 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.

Contact:

John Bluth

Cempra, Inc.

+1 984 209 4534

jbluth@cempra.com

Investor Contact:

Robert Uhl

Westwicke Partners, LLC

+1 858 356 5932

robert.uhl@westwicke.com

Media Contact:

Melyssa Weible

Elixir Health PR

+1 201 723 5805

mweible@elixirhealthpr.com

Primary Logo

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