COWEN AND COMPANY

Quick Take

Cempra — Outperform (1)

CEMP: $6.01

Quick Take: Phase III Trial In CABP Begins; Strong Momentum Continues

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This morning, Cempra announced the initiation of the global Phase III trial of oral solithromycin (CEM-101) in patients with community-acquired bacterial pneumonia (CABP). The trial will compare solithromycin with moxifloxicin in approximately 800 patients and the primary endpoint will be non-inferiority in early response at 72 hours. Cempra expects to complete the trial in 1H14.

The initiation of the oral solithromycin Phase III trial comes just days after Cempra initiated a Phase II clinical trial to evaluate CEM-102, the company's second candidate in the pipeline and a proprietary dosing regimen for fusidic acid, in patients with prosthetic joint infections (PJIs). Data from both trials, if positive, will support regulatory filings for solithromycin and CEM-102.

We remain bullish on Cempra shares based on the continued strong momentum and reiterate our Outperform rating.

Phase III Oral Solithromycin Pivotal Trial Likely To Succeed

Active comparator sets a lower bar. The primary endpoint follows the recently proposed FDA guidelines on CABP clinical studies. Solithromycin demonstrated non-inferiority to levofloxacin in the successfully completed Phase II trial. Numerous clinical studies compared moxifloxacin to levofloxacin and demonstrated no significant difference. However, these studies have reported higher rates of adverse events with moxifloxacin treatment. Therefore, we believe solithromycin will perform well on the efficacy side while outperforming on the safety side in comparison to moxifloxacin in the Phase III trial.

Enrollment is progressing well. Clinical sites will cover multiple geographic areas and will include approximately 30 sites that participated in the Phase II study. Cempra has recruited a highly competent team with great enthusiasm and the CRO to be used worked on the development of Ceftaroline (Teflaro).

No effects on QTc have been observed. Cempra has conducted extensive studies on the safety profile of solithromycin and no heart-related issues have been detected. Cempra plans to submit QT study designs for both oral and I.V. formulations and expects to complete the studies prior to the initiation of the I.V. to oral step-down study, which will be the second registration study.

I.V. to oral step-down study is being planned. Based on the positive results from the Phase I I.V. study of solithromycin, Cempra expects to have the end-of-Phase II

meeting with the FDA in 1H13 and the company plans to initiate the first I.V.-to-oral Phase III study in 2013, upon availability of a partnership or with additional financing. The combination of the oral Phase III study and one I.V.-to-oral step-down Phase III study will potentially be sufficient to support an NDA filing.

Oral Solithromycin Phase III Trial Design

The double-blind, active-comparator study will enroll approximately 800 patients with PORT-II to PORT-IV CABP. Patients will be randomized to receive once daily oral dosing of either solithromycin for five days or moxifloxacin for seven days. Solithromycin will be administered at a loading dose of 800mg on day one and subsequently at the maintenance dose of 400mg for the remaining four days. This is the same dosing regimen as in the completed Phase II trial. In comparison, moxifloxacin will be dosed at 400mg on all seven days.

Pneumonia Patient Outcomes Research Team (PORT) Score

PORT scores indicate whether patients can be treated at home as outpatients or in hospitals as inpatients, with PORT I designating those who can be sent home on oral antibiotics, PORT II-III for those who can be sent home with I.V. antibiotics or treated and monitored for 24 hours in the hospital, and PORT IV-V for patients who must be hospitalized for the treatment. According to the new FDA guidelines, oral CABP trials can enroll no PORT I patients and must enroll at least 50% PORT III patients, whereas I.V. CABP trials can enroll up to 25% PORT II patients and must enroll at least 25% PORT IV-V patients.

Addendum

STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
CEMP	Cempra

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(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

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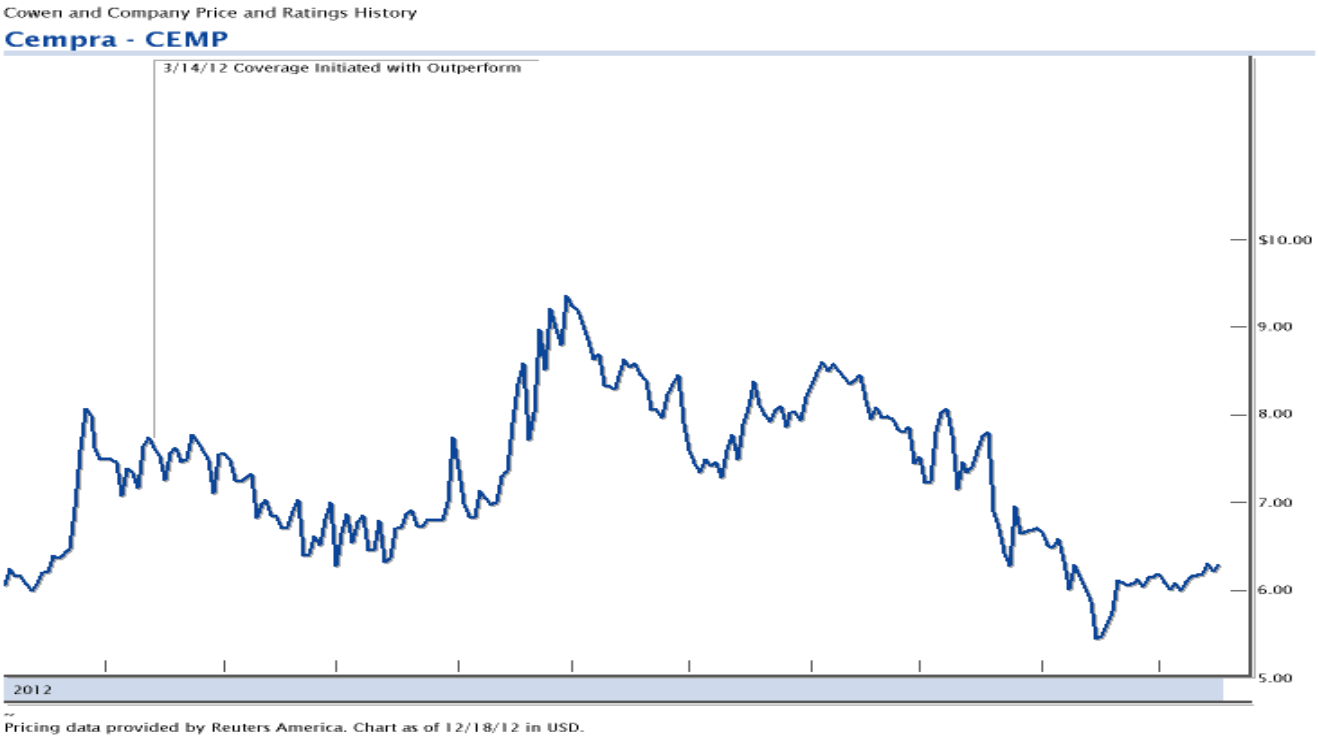
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Cempra - CEMP
3/14/12 Coverage Initiated with Outperform
$10.00
9.00
8.00
7.00
6.00
5.00
2012
Pricing data provided by Reuters America. Chart as of 12/18/12 in USD.