

Quick Take

Cempra — Outperform (1)

CEMP: \$6.21

Quick Take: Phase II Trial Initiated For CEM-102 In PJI

December 18, 2012

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Cempra has announced the initiation of the Phase II clinical trial to evaluate CEM-102, the company's proprietary dosing regimen for fusidic acid, in patients with prosthetic joint infections (PJIs). This progress is in line with company guidance and the previously guided for the announcement of results in 1H14. We believe the primary endpoint of the Phase II trial has set a low bar for CEM-102 and based on the demonstrated clinical profile of CEM-102 to date, we are optimistic that the Phase II trial will succeed.

We view the timely initiation of this Phase II trial as a strong positive catalyst. Cempra is developing CEM-102 as an oral therapy for the treatment of infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA). Linezolid, currently the only oral antibiotic for MRSA infections, cannot be taken chronically since long term use (>28 days) was associated with severe peripheral and optic neuropathy and peripheral neuropathy that did not resolve even after termination of treatment. In contrast, CEM-102 has demonstrated a long history of efficacy and safety with little resistance outside the U.S.

We remain bullish on Cempra shares based on the progress of the CEM-program and reiterate our Outperform rating.

Trial Design

The Phase II clinical trial is an open-label study that will enroll 50 patients with PJI. The patients will be randomized to receive either oral CEM-102 combined with rifampin or current standard of care, which is I.V. antibiotic therapy with antibiotics such as vancomycin, nafcillin or cefazolin. The primary endpoint is demonstration of infection-free status at 12 weeks following initiation of therapy. Long-term monitoring for infection relapse or recurrence will be conducted for a subsequent two years.

Proprietary Dosing Regimen Minimizes Resistance

Fusidic acid typically needs to be combined with another antimicrobial such as rifampicin when treating serious MRSA infections to avoid bacteria resistance. Cempra has developed a proprietary dosing regimen with a high loading dose followed by a low maintenance dose to further minimize possible bacterial resistance.

Cempra's proprietary Taksta dosing regimen consists of a 1500mg BID loading of

Please see addendum of this report for important disclosures.

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fusidic acid followed by a 600mg maintenance dose. The initial higher concentration of fusidic acid in the bloodstream at the beginning of the treatment can rapidly reduce the bacterial load, thereby limiting resistance development, whereas the low dose used for maintenance can increase patient tolerability and reduce adverse GI related events such as nausea and vomiting. Cempra has submitted a patent application for the dosing regimen which is currently pending at the USPTO.

Demonstrated Safety And Efficacy Of CEM-102

An Australian study with a similar design evaluated oral fusidic acid in 20 patients with staphylococcal prosthetic joint infections. Two patients received change of treatment due to severe nausea and the remaining 18 patients demonstrated no evidence of treatment failure, within which 16 patients retained their original prosthesis with no evidence of infection after 26 months of follow-up.

Cempra has also completed a Phase II trial that compared CEM-102 to linezolid for the treatment of acute bacterial skin and skin structure infection (ABSSSI). The trial demonstrated comparable efficacy, safety and tolerability of CEM-102 to linezolid.

Potential Orphan Drug Status

PJIs are estimated to occur at an overall annual incidence rate of approximately 10,000 in the U.S. Given the limited number of patients who are affected by this indication, Cempra plans to apply for Orphan Drug Status, which if approved will provide Cempra with favorable pricing and seven years of exclusivity in marketing CEM-102.

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.

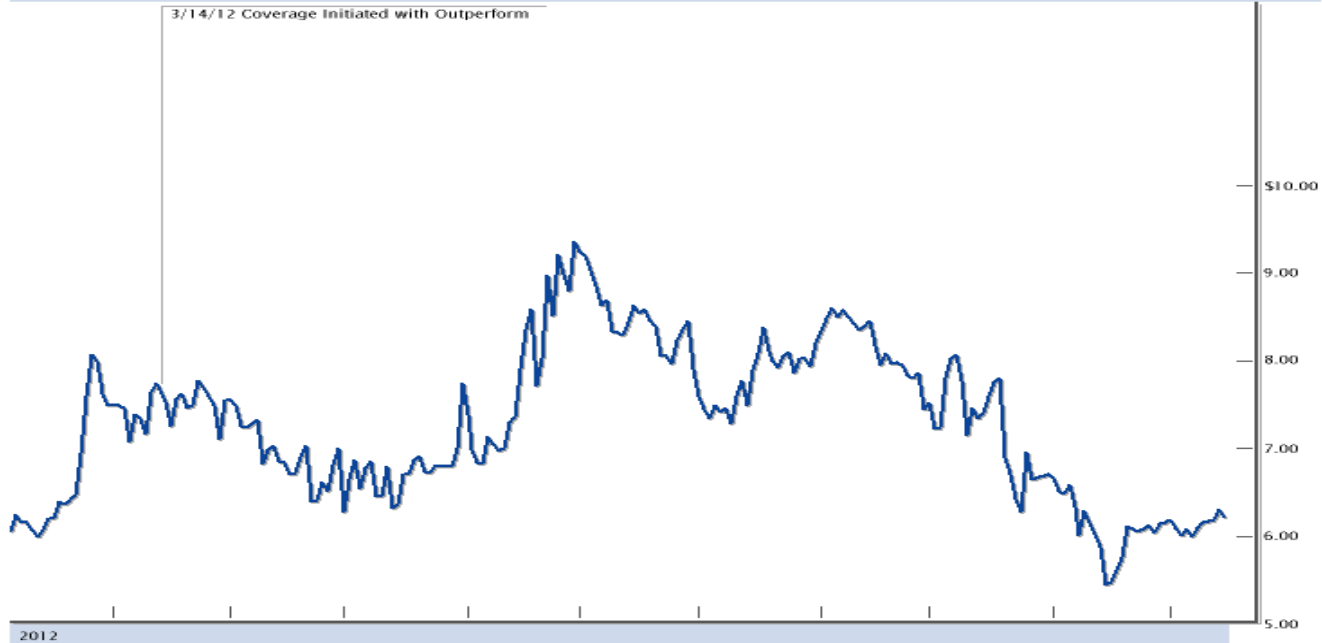
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Cempra - CEMP



Pricing data provided by Reuters America. Chart as of 12/17/12 in USD.