



Data From Optimer's Second Fidaxomicin Phase 3 Study for the Treatment of *Clostridium Difficile* Infection (CDI) Featured in Oral Presentation at Digestive Disease Week

Fidaxomicin Associated with Lower Recurrence Rates and Higher Global Cure Rates in Subjects Receiving Concomitant Antibiotics

SAN DIEGO, May 4, 2010 /PRNewswire via COMTEX News Network/ -- Optimer Pharmaceuticals, Inc. (Nasdaq: OPTR) announced the presentation of new data from its second fidaxomicin Phase 3 clinical study in patients with *Clostridium difficile* infection (CDI). The data, presented by Stuart Johnson, M.D. during an oral session at the annual meeting of Digestive Disease Week (DDW) in New Orleans, indicated that treatment with fidaxomicin significantly improved the recurrence rate and global cure rate in CDI patients requiring concomitant antibiotics, compared to vancomycin.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20090413/LA97352LOGO>)

Many patients have persistent infections or develop new infections during the course of CDI treatment. In these situations, additional concomitant antibiotics often must be administered, which can have a negative effect by increasing recurrences and lowering global cures of CDI. In the study presented by Dr. Johnson, 59% of subjects were receiving concomitant antibiotics during CDI treatment. New data from analyses of the study showed that, among subjects who were receiving concomitant antibiotics, treatment with fidaxomicin resulted in a significantly lower recurrence rate compared to treatment with vancomycin (17.6% vs. 29.5%, $p=0.027$) and an improved global cure rate compared to treatment with vancomycin (67.5% vs. 53.4%, $p=0.020$). These results confirm findings from the first fidaxomicin Phase 3 study and suggest that, even when concomitant antibiotics are administered, fidaxomicin may be more effective than vancomycin in the treatment of CDI.

"The data presented today confirm the benefits of fidaxomicin in CDI treatment even when patients require concomitant antibiotics, a common scenario during CDI treatment," said Stuart Johnson, M.D., Infectious Disease Section, Loyola University Medical Center and Hines VA Hospital. "More importantly, fidaxomicin is the first CDI antibiotic treatment to show significantly lower recurrence rates over the only FDA approved therapy for CDI."

Dr. Johnson also presented the previously announced top-line results, baseline demographic, disease characteristics, and data related to subgroup analysis of the BI/NAP1/027 strain and the non-BI/NAP1/027 strains of *Clostridium difficile*.

Fidaxomicin Clinical Study Design

The second fidaxomicin Phase 3 clinical study was a multi-center, randomized, double-blind clinical trial, which enrolled 535 adult subjects. Subjects with confirmed CDI received either fidaxomicin (200 mg q12h) or Vancocin (125 mg q6h). This study was conducted in approximately 100 clinical sites throughout North America and Europe. The study was designed to evaluate safety and compare the response to treatment in subjects during and after a 10-day course of therapy. Non-inferiority in clinical cure (defined as patients requiring no further CDI therapy two days after completion of study medication, as determined by the investigator) compared to Vancocin was the primary endpoint. If cured, subjects were monitored for a subsequent four-week period to evaluate recurrence, which was a secondary endpoint. Global cure, also a secondary endpoint, was defined as patients who were cured and did not have a recurrence during this subsequent four-week period.

About *Clostridium difficile* Infection

CDI has become a significant medical problem in hospitals, long-term care facilities, and in the community. It is a serious illness caused by infection of the inner lining of the colon by *C. difficile* bacteria, which produces toxins that cause inflammation of the colon, severe diarrhea and, in the most serious cases, death. Patients typically develop CDI from the use of broad-spectrum antibiotics that disrupt normal gastrointestinal (gut) flora, and thus allowing *C. difficile* bacteria to flourish.

Current therapeutic options for CDI include the off-label use of metronidazole and oral vancomycin, the only FDA-approved treatment. However, approximately 20% to 30% of CDI patients who initially respond to these treatments experience a clinical recurrence following cessation of antibiotic administration.

Primary risk factors for CDI include broad-spectrum antibiotic use (such as cephalosporins and fluoroquinolones), advanced age (over 65) and emerging hyper-virulent strains (BI/NAP1/027, 078, 001) of *C. difficile*. Increasing incidence, higher treatment failures and recurrence with current therapies have resulted in greater awareness and concern of CDI among

medical professionals and public health officials.

About Fidaxomicin

Fidaxomicin is the first in a new class of antibiotics called macrocycles, which inhibit the bacterial enzyme RNA polymerase, resulting in the death of *C. difficile*. The narrow-spectrum profile of fidaxomicin may eradicate *C. difficile* selectively with minimal disruption to the normal intestinal flora, while most broad-spectrum antibiotics, including metronidazole and vancomycin, disrupt these flora. Fidaxomicin may facilitate the return of the normal physiological conditions in the colon and reduce the probability of CDI recurrence.

About Optimer Pharmaceuticals

Optimer Pharmaceuticals, Inc. is a biopharmaceutical company focused on discovering, developing and commercializing innovative anti-infectives to treat serious infections and address unmet medical needs. Optimer has two late-stage anti-infective product candidates under development. Fidaxomicin is a narrow spectrum antibiotic being developed for the treatment of *Clostridium difficile* infection. Optimer has reported positive top-line results from two Phase 3 trials of fidaxomicin. Pruvex(TM) is a prodrug in the fluoroquinolone class of antibiotics being developed as a treatment for infectious diarrhea. Optimer has also successfully completed two Phase 3 trials with Pruvex. Additional information can be found at <http://www.optimerpharma.com>.

Forward-looking Statements

Statements included in this press release that are not a description of historical facts are forward-looking statements including, without limitation, all statements related to fidaxomicin, the incidence and anticipated effects of CDI, the efficacy of current CDI treatments and the efficacy and potential benefits of fidaxomicin. Words such as "believes", "anticipates", "plans", "expects", "may", "intend", "will", "goal" and similar expressions are intended to identify forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Optimer that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in Optimer's business including, without limitation, risks relating to the development of alternative treatments for, or means of preventing, CDI and other risks detailed in Optimer's filings with the Securities and Exchange Commission.

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