



Positive Results from Optimer Pharmaceuticals' Second Phase 3 Study of Fidaxomicin for the Treatment of *Clostridium difficile* Infection (CDI) Presented at ECCMID

BI/NAP1/027 Subgroup Analyses Shows a Clinically Meaningful Reduction in Recurrence Rates for Fidaxomicin versus Vancocin(R)

SAN DIEGO, April 10, 2010 /PRNewswire via COMTEX News Network/ -- Optimer Pharmaceuticals, Inc. (Nasdaq: OPTR) announced that the top-line results from its second fidaxomicin Phase 3 clinical study in patients with *Clostridium difficile* infection (CDI) were presented today at the 20th Annual European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Vienna, Austria.

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

Clinical investigator Derrick Crook, M.D. presented the positive top-line results that the Company had previously announced in February 2010. In the trial, fidaxomicin met the primary endpoint of non-inferiority in clinical cure compared to Vancocin(R). Importantly, fidaxomicin also had significantly lower recurrence rates compared to Vancocin ($p = 0.002$), and significantly higher global cure rates (defined as cure with no recurrence within four weeks of completing therapy) compared to Vancocin ($p < 0.001$). The robust results from this second fidaxomicin Phase 3 trial confirm the results from the first fidaxomicin Phase 3 trial. Together these trials enrolled more than 1,100 subjects thus making them the two largest comparative studies ever conducted against Vancocin in CDI.

"Fidaxomicin offers potential advantages over existing therapies as a single agent that can provide a high cure rate and fewer recurrences for *Clostridium difficile* infection," said Dr. Crook, M.D., Consultant Microbiologist/Infectious Diseases and Professor of Infectious Diseases and Microbiology, Experimental Medicine Division, Nuffield Department of Clinical Medicine (NDM), University of Oxford. "Moreover, we found that even in patients with the hypervirulent BI/NAP1/027 subtype, fidaxomicin provided an improvement in recurrence rates compared to the currently approved treatment."

Additional data presented for the first time by Dr. Crook included a subgroup analysis of the BI/NAP1/027 strain and the non-BI/NAP1/027 strain showing clinical cure, recurrence and global cure rates for fidaxomicin compared to Vancocin(R). Most notably, Fidaxomicin showed a clinically meaningful reduction in recurrence rates and higher global cure rates compared to Vancocin in both strain type subgroups. Clinical cure rates for fidaxomicin and Vancocin were similar in these two strain type subgroups.

Per Protocol (microbiologically evaluable)	Fidaxomicin (200mg bid)	Vancocin(R) capsules (125mg qid)	p-value
Recurrence Rates by Subgroup			
BI/NAP1/027	22.2% (10/45 patients)	42.1% (16/38 patients)	0.052
non-BI/NAP1/027	9.0% (9/100)	25.6% (23/90)	0.002
modified Intent-to-Treat (mITT)			
Recurrence Rates by Subgroup			
BI/NAP1/027	22.2% (12/54 patients)	38.3% (18/47 patients)	0.078
non-BI/NAP1/027	9.2% (11/120)	27.8% (30/108)	<0.001
Per Protocol (microbiologically evaluable)	Fidaxomicin (200mg bid)	Vancocin(R) capsules (125mg qid)	p-value

Global Cure Rates by Subgroup			
BI/NAP1/027	69.1% (38/55 patients)	51.9% (27/52 patients)	0.069
non-BI/NAP1/027	85.5% (100/117)	66.1% (74/112)	0.001
modified Intent-to-Treat (mITT)	Fidaxomicin (200mg bid)	Vancocin(R) capsules (125mg qid)	p- value
Global Cure Rates by Subgroup			
BI/NAP1/027	64.6% (42/65 patients)	50.9% (29/57 patients)	0.125
non-BI/NAP1/027	83.2% (109/131)	63.4% (78/123)	<0.001

Dr. Crook also presented baseline demographic and disease characteristics of study participants which were similar between the fidaxomicin and Vancocin arms. The BI/NAP1/027 strain was identified in 32% of subjects in the second Phase 3 study. 54% of the study participants were over the age of 65, 68% were in-patients, and 15% had a prior episode of CDI. An average of 7.5 bowel movements per day was observed among all subjects. The incidence of adverse events and serious adverse events was similar in the fidaxomicin and Vancocin arms.

In a separate poster presentation, Mark A. Miller, M.D., head of the Division of Infectious Diseases, Chair of the Infection Prevention and Control Unit at the Jewish General Hospital in Montreal, Quebec, Canada, presented analyses from the first fidaxomicin Phase 3 clinical study in patients with CDI regarding three of the 14 severity criteria specified in the CDI treatment guidelines recently published by The European Society of Clinical Microbiology and Infectious Diseases (ESCMID). Three of ESCMID's 14 severity criteria (temperature, leukocyte count and serum creatinine) had been routinely collected from all subjects in this study and were examined in relationship to clinical cure, recurrence, global cure, and time to resolution of diarrhea (TTROD). According to the ESCMID guidelines, patients with one or more of the criteria could be classified as a severe CDI patient. Out of 596 subjects from this study, 155, or 26%, had one or more of the three ESCMID severity criteria monitored in the study. A validated severity index, score, or categorization system does not exist at the present time for predicting CDI outcomes based on risk factors. The analyses indicated that the three ESCMID criteria monitored in the study were useful in predicting CDI treatment outcomes.

Fidaxomicin Clinical Study Design

The second Phase 3 trial 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. Pruvel(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 Pruvel. 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.

Contacts

Optimer Pharmaceuticals, Inc.
Christina Donaghy, Corporate Communications Manager
John D. Prunty, Chief Financial Officer & VP Finance
858-909-0736

Porter Novelli Life Sciences
Jason I. Spark, Vice President
619-849-6005

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