



Optimer Pharmaceuticals Announces Positive Results From Second Fidaxomicin Phase 3 Study in Patients With Clostridium Difficile Infection

Data Confirms Fidaxomicin Provided Statistically Significant Difference in Recurrence Rates and Global Cure Rates vs. Vancocin(R)

SAN DIEGO, Feb 04, 2010 /PRNewswire via COMTEX News Network/ -- Optimer Pharmaceuticals, Inc. (Nasdaq: OPTR) today announced positive top-line results from the second of two pivotal Phase 3 trials evaluating the safety and efficacy of fidaxomicin (OPT-80) in patients with *Clostridium difficile* Infection (CDI). This study was conducted in approximately 100 clinical sites throughout North America and Europe. The Company plans to use data from this study to support submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2010.

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

The trial met the primary endpoint of non-inferiority with 91.7% of patients treated with fidaxomicin (per protocol population) achieving clinical cure vs. 90.6% for Vancocin, the only FDA-approved therapy for CDI. Importantly, fidaxomicin also had significantly lower recurrence rates and higher global cure rates (defined as cure with no recurrence within four weeks of completing therapy) compared to Vancocin. Only 12.8% of patients treated with fidaxomicin experienced a recurrence vs. 25.3% of patients treated with Vancocin ($p = 0.002$). Additionally, 79.6% of patients treated with fidaxomicin achieved a global cure versus 65.5% of patients treated with Vancocin ($p < 0.001$). As in the first Phase 3 trial, fidaxomicin was well-tolerated in the study.

"The robust results from our second Phase 3 trial of fidaxomicin confirm the results of our first Phase 3 trial showing that fidaxomicin has the potential to be a first-in-class drug for the treatment of *Clostridium difficile* infection. There are currently limited treatment options for this disease and we believe there is a need for innovative alternatives," said Michael N. Chang, Ph.D., Optimer's Chief Executive Officer. "A higher global cure demonstrates the potential for fidaxomicin to improve patient outcomes, reduce repeat visits to the hospital and reduce person-to-person transmission, which may result in a lower cost burden to the healthcare system."

"The growing incidence of CDI in hospitals, long-term care facilities, and in the community, which we believe is caused in part by the use of broad-spectrum antibiotics and an aging population, create a need for new CDI therapies," said Sherwood L. Gorbach, M.D., Optimer's Chief Medical Officer. "These results show that a single, effective antibiotic can provide a high cure rate and simultaneously, a low recurrence rate. We believe fidaxomicin demonstrates a clinically significant difference and offers substantial benefits to CDI patients and the medical community."

Top-line trial results are summarized in the table below.

Per Protocol (microbiologically evaluable)	Fidaxomicin (200mg bid)	Vancocin(R) capsules (125mg qid)	p-value	95% Confidence Interval of Difference
Clinical Cure	91.7% (198/ 216 patients)	90.6% (213/ 235 patients)	NA	(-4.3, 6.3)
Recurrence	12.8% (23/180)	25.3% (46/182)	0.002	(-20.3, -4.4)
Global Cure	79.6% (172/216)	65.5% (154/235)	<0.001	(5.9, 22.1)

modified Intent-to-Treat (mITT)	Fidaxomicin (200mg bid)	Vancocin(R) capsules (125mg qid)	p-value	Confidence Interval of Difference
Clinical Cure	87.7% (221/252 patients)	86.8% (223/257 patients)	NA	(-4.9, 6.7)
Recurrence	12.7% (28/221)	26.9% (60/223)	<0.001	(-21.4, -6.8)
Global Cure	76.6% (193/252)	63.4% (163/257)	0.001	(5.2, 20.9)

NA = Not Applicable (trial met non-inferiority endpoint)

The Per Protocol (Microbiologically Evaluable) Population is the patient group with CDI confirmed by diarrhea with a positive toxin assay, that met all inclusion/exclusion criteria, and that received at least 3 days of therapy if deemed a failure or at least 8 days of therapy if deemed a cure.

The Modified Intent-to-Treat Population is the patient group with CDI confirmed by diarrhea with a positive toxin assay and received at least one dose of study medication.

The second fidaxomicin Phase 3 trial (Protocol 101.1.C.004) and the first fidaxomicin Phase 3 trial (Protocol 101.1.C.003) are the two largest comparative studies ever conducted against Vancocin in CDI. Additional data from this study will be presented at medical conferences in the near future.

In November 2008, the Company reported positive data from the first Phase 3 trial, which showed that fidaxomicin met its primary endpoint of non-inferiority of clinical cure compared to Vancocin. In addition, patients treated with fidaxomicin in the first Phase 3 trial also experienced a reduction in CDI recurrence compared to Vancocin (p=0.004) and had a higher global cure compared to Vancocin (p=0.006). The first Phase 3 study was conducted at sites throughout North America.

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.

Conference Call Information

Optimer will host a conference call for the investment community today beginning at 2:00 p.m. Pacific time (5:00 p.m. Eastern time) to discuss the results of the fidaxomicin Phase 3 trial and answer questions.

The conference call may be accessed by dialing (888) 516-2377 for domestic callers and (719) 325-2339 for international callers. The conference call will be webcast live under the Investors section of Optimer's website at www.optimerpharma.com.

About Optimer Pharmaceuticals

Optimer Pharmaceuticals, Inc. is a biopharmaceutical company focused on discovering, developing and commercializing innovative anti-infective products to treat serious infections and address unmet medical needs. Optimer has two late-stage anti-infective product candidates under development. Fidaxomicin, formerly known as OPT-80, is the only antibiotic therapy currently in Phase 3 worldwide clinical development for *Clostridium difficile* infection. Pruve!™ (prulifloxacin) is an antibiotic which has completed two Phase 3 clinical trials for the treatment of infectious diarrhea in travelers. 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, the efficacy and potential benefits of fidaxomicin and expected regulatory filings. 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 timing, preparation and submission of applications for marketing approval with the FDA, 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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