



Optimer Pharmaceuticals Submits Fidaxomicin Marketing Authorization Application for the Treatment of *Clostridium difficile* Infection

SAN DIEGO, July 29, 2010 /PRNewswire via COMTEX News Network/ -- Optimer Pharmaceuticals, Inc. (Nasdaq: OPTR) today announced that it has submitted a Marketing Authorization Application (MAA) for fidaxomicin to the European Medicines Agency (EMA) under the European Union's Centralized Procedure. Optimer is seeking approval to market fidaxomicin for the treatment of patients with *Clostridium difficile* infection (CDI).

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"The submission of our fidaxomicin MAA represents a significant step in making this innovative medicine available to European patients and to join the many on-going efforts to improve health care cost in the EU. *Clostridium difficile* infection is a growing disease and major unmet medical need. We are excited with the opportunity it represents for our company. Europe is an important market opportunity for us as the increased awareness of CDI over the past several years has led to improved diagnosis and reporting of the disease," said Pedro Lichtinger, President and CEO of Optimer. "As more resources are committed to understanding CDI in Europe, its prevalence and the importance of treating this disease in this market will be better appreciated. This MAA is the next step towards making fidaxomicin part of the solution to what appears to be an expanding clinical problem in the European market."

Optimer also plans to submit a new drug application to the FDA in 2010 for marketing approval of fidaxomicin in the U.S.

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.

Fidaxomicin Clinical Studies

The two fidaxomicin Phase 3 clinical studies were multi-center, randomized, double-blind trials, which enrolled a total of 1,164 adult subjects. Subjects with confirmed CDI received either fidaxomicin (200 mg q12h) or Vancocin(R) (125 mg q6h), the only FDA approved product for the treatment of CDI. These studies were designed to evaluate safety and compare the response to treatment in subjects during and after a 10-day course of therapy. The primary endpoint was non-inferiority compared to Vancocin in clinical cure (defined as patients requiring no further CDI therapy two days after completion of study medication, as determined by the investigator). 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. In both of these studies, fidaxomicin achieved its primary endpoint of non-inferiority compared to Vancocin. Fidaxomicin was also statistically superior to Vancocin in global cure rate and in reducing recurrences of CDI.

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 use of metronidazole (not an approved therapy for CDI in the U.S.) 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 exposure to 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 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 is preparing regulatory submissions for two anti-infective product candidates. Fidaxomicin is a narrow spectrum antibiotic being developed for the treatment of *Clostridium difficile* infection. Pruvel(TM) is a prodrug in the fluoroquinolone class of antibiotics being developed as a treatment for infectious diarrhea. 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 the development, potential therapeutic indication and advantages of fidaxomicin, the incidence and effects of CDI, the efficacy of current CDI treatments and the efficacy and potential benefits of fidaxomicin, potential regulatory approval of fidaxomicin, fidaxomicin's ability to offer CDI patients new treatment options and the awareness of CDI among healthcare professionals. 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, whether regulatory authorities will review or approve Optimer's applications for marketing approval, the timing of any marketing approvals, Optimer's ability to commercialize any products for which it receives marketing approval and other risks detailed in Optimer's filings with the Securities and Exchange Commission.

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