



Data Presented at ECCMID Illustrate Risk Factors for Negative Outcomes in *C. Difficile* Patients

SAN DIEGO, May 10, 2011 /PRNewswire/ -- Optimer Pharmaceuticals, Inc. (NASDAQ: OPTR) today announced the presentation of two abstracts at the 21st European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) conference in Milan, Italy highlighting additional analyses of the Phase 3 data of DIFICID™ (fidaxomicin) for the treatment of *Clostridium difficile* infection (CDI). The data resulted from analysis of specific risk factors associated with negative outcomes in patients with CDI, including immunosuppression and alcohol abuse.

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The first study analyzed pooled data from two Phase 3 clinical trials of DIFICID for the treatment of CDI and determined that immunosuppression is associated with higher death and lower CDI cure rates. The analysis also demonstrated that the rate of CDI recurrence remained substantially lower among immunosuppressed patients treated with DIFICID vs. vancomycin (16% vs. 27%; $p < 0.01$). Independent of treatment regimen, mortality was higher among patients with a net state of immunosuppression (11% vs. 3%; $p < 0.01$), patients receiving immunosuppressive medications (9% vs. 6%; $p < 0.04$), patients receiving systemic steroids (14% vs. 5%; $p < 0.01$) or moderate or high-dose steroids (25% vs. 5%; $p < 0.01$), and patients with neutropenia (16% vs. 6%; $p < 0.01$). Independent of treatment regimen, cure rates were lower among immunosuppressed patients, particularly those receiving moderate or high-dose steroids (75% vs. 88%; $p < 0.01$). In a multivariate analysis, immunosuppression was independently associated with a higher mortality rate from CDI and a lower cure rate, but was not associated with a higher recurrence rate. The study, titled "Immunosuppression and the risk of death, cure rates and disease recurrence among patients with *Clostridium difficile* infection (CDI)," was featured in an oral presentation on May 10.

"Any number of variables can cause a patient to have a less effective immune system, including the use of certain medicines, neutropenia or background illness, and each of these variables is significantly associated with an increase in death and a lower cure rate in patients with *C. difficile*," noted Sherwood L. Gorbach, M.D., Chief Scientific Officer for Optimer. "Notably, regardless of patients' level of immunosuppression, the rate of CDI recurrence remained substantially lower among patients treated with DIFICID."

The second study, titled "*Clostridium difficile* recurrence (CDR), alcohol consumption, and the effect of fidaxomicin vs. vancomycin," analyzed 794 patients from the same two Phase 3 clinical trials. Independent of treatment regimen, the study determined that alcohol abuse, defined as consumption of more than two alcoholic drinks a day, is associated with a higher rate of CDI recurrence (33.3% vs. 17.9%; $p < 0.01$), and particularly recurrence that occurs one to 15 days after stopping an antibiotic treatment regimen (26.1% vs. 12.1%; $p < 0.01$). Compared to vancomycin, DIFICID was associated with lower recurrence rates regardless of alcohol consumption.

About DIFICID™

DIFICID™ (fidaxomicin), if approved, would be the first new antibiotic for the treatment of *Clostridium difficile* infection (CDI) in nearly 30 years. In two Phase 3 trials for the treatment of CDI, fidaxomicin was non-inferior in clinical cure when compared to vancomycin, the only FDA approved product for CDI. DIFICID also demonstrated superiority to vancomycin in global cure, which is defined as a cure without recurrence, or a sustained cure, through the end of the follow up period. This difference was driven by DIFICID's lower rates of relapse of diarrhea following cessation of the CDI treatment.

About *Clostridium difficile* Infection (CDI)

Clostridium difficile infection (CDI), commonly referred to as "C. difficile" or "c-diff", has become a significant medical problem in hospitals, long-term care facilities, and in the community and is estimated to afflict more than 700,000 people each year in the U.S. It is a serious illness resulting from infection of the inner lining of the colon by *C. difficile* bacteria, which produce 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, thus allowing *C. difficile* bacteria to flourish and produce toxins.

Current therapeutic options for CDI include the off-label use of metronidazole and oral vancomycin, the latter being the only FDA-approved treatment. However, approximately 20% to 30% of CDI patients who initially respond to these treatments experience a clinical recurrence, defined as a relapse or re-establishment of diarrhea, following cessation of the CDI treatment.

Primary risk factors for CDI include broad-spectrum antibiotic use (such as cephalosporins and fluoroquinolones), older age (over 65) and exposure to emerging hyper-virulent strains (BI/NAP1/027, 078, 001) of *C. difficile*. The rise in incidence of CDI, along with high rates of both treatment failures and recurrences with current therapies have resulted in greater awareness and concern about CDI among medical professionals and public health officials. You may learn more about CDI at www.cdiinfo.org, a website of Optimer.

About Optimer Pharmaceuticals

Optimer Pharmaceuticals, Inc. is a biopharmaceutical company focused on discovering, developing and commercializing innovative hospital specialty products that have a positive impact on society. Optimer has two anti-infective product candidates in development, DIFICID™ (fidaxomicin) and Pruvel™ (prulifloxacin). DIFICID is a narrow spectrum antibiotic being developed for the treatment of *Clostridium difficile* infection (CDI). The FDA granted the Company's request for six-month Priority Review of Optimer's NDA for DIFICID, and has assigned a Prescription Drug User Fee Act (PDUFA) goal date of May 30, 2011. The Company also filed a MAA with the European Medicines Agency (EMA) for DIFICID. Pruvel 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>.

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