



## Optimer to Provide DIFICID™ Launch Update at Morgan Stanley Global Healthcare Conference

SAN DIEGO, Sept. 12, 2011 /PRNewswire/ -- Optimer Pharmaceuticals, Inc. (NASDAQ: OPTR) announced that the Company will provide an update on the DIFICID™ (fidaxomicin) tablets launch at the Morgan Stanley Global Healthcare Conference taking place in New York City. Pedro Lichtinger, Optimer's President and CEO, will comment on the DIFICID launch tomorrow, September 13, during a webcasted fireside chat at 8:00 AM ET. DIFICID was approved by the U.S. Food and Drug Administration in May of 2011 for the treatment of *Clostridium difficile*-associated diarrhea (CDAD) in adults 18 years of age and older. CDAD is a significant medical problem in hospitals and long-term care facilities, and DIFICID is the first antibacterial drug approved for the treatment of CDAD in 25 years.

(Logo: <http://photos.prnewswire.com/prnh/20090413/LA97352LOGO> )

"We believe the Optimer strategy is proving highly impactful, with DIFICID sales exceeding published analyst expectations in the initial stages of the launch. While early in the launch, we view it as a major success to date. We are committed to maintaining this momentum as the launch matures," said Pedro Lichtinger, president and CEO of Optimer Pharmaceuticals. "The growing evidence of the value of DIFICID to patients, hospitals and payers is being well received by practitioners and other stakeholders. Supported by DIFICID's clinical strength and value proposition, we believe the combined Optimer/Cubist field presence is having a material impact on accelerating prescriptions and formulary adoption."

There are several key components comprising the DIFICID launch effort and Optimer plans to review progress to date for each of those components.

### 1. DIFICID Sales

For the period of July 19, the date of DIFICID's first sales, through September 2, Optimer estimates DIFICID gross sales of \$3.9 million representing over 1380 treatments. This sales figure is based on DIFICID shipped from Optimer's wholesalers to hospital pharmacies, retail pharmacies and long-term care facilities. In addition, Optimer has delivered 124 treatments through its Patient Assistance Program during the same time period.

- Optimer's sales efforts, supported by its co-promotion partner, Cubist Pharmaceuticals, represent the only active marketing effort for a drug approved to treat CDAD.
- Optimer and Cubist's combined efforts are reaching about 1,800 hospitals, covering over 85% of hospital CDAD cases.
- DIFICID's clinical strength and value proposition is thought to be supporting early adoption by specialists (e.g. Gastroenterologists, Oncologists, and Internists).

### 2. Hospital Formularies

Ninety-nine hospitals have already added DIFICID to their formularies. One hundred sixty-eight formulary committee reviews are scheduled over the next few months, with hundreds of additional reviews expected by year end. Of the 99 hospitals with DIFICID already on formulary, 23 provide for unrestricted access, 68 require an Infectious Disease specialist consultation (with some hospitals allowing a Gastroenterologist consultation instead), and 8 hospitals require a prior authorization.

- Approximately 350 hospitals have ordered and dispensed DIFICID in their facilities.
- For the week ending September 2, 39% of hospital orders were repeat orders (27% of total orders were repeat orders).

### 3. Patient Access

During the first phase of the DIFICID launch Optimer believes there is strong payer early adoption. Optimer has secured initial patient access to DIFICID generally comparable to Vancocin. As the launch progresses, Optimer's goal is to secure continuing broad access comparable to Vancocin.

- 70% of targeted commercial health plan lives currently have access to DIFICID.
- Labeler code added to Medicare Part D Coverage Gap Discount Program.

- Medicaid Drug Rebate Agreement is executed.
- Federal Supply Schedule interim agreement in place.
- Established patient assistance program (PAP) designed to provide free drug to qualified patients in need.
  - Access facilitated while payer coverage policies being established.

#### 4. Medical Affairs/Education

Optimer's medical affairs team has been communicating with the medical community to help educate physicians on CDAD overall and the clinical benefits DIFICID can potentially have in treating CDAD patients. The medical affairs team is leading:

- Robust peer-reviewed publication efforts to communicate DIFICID's clinical attributes as well as scientific data.
- An active presence at key medical and scientific congresses across a range of medical specialties.
- In collaboration with Cubist, Optimer expects to have conducted over 500 medical education meetings reaching over 15,000 physicians by the end of the year.

#### The Burden of *Clostridium Difficile*-Associated Diarrhea (CDAD)

Current estimates suggest CDAD may affect more than 700,000 people in the U.S. each year, though the incidence may be higher as many cases are believed to be undiagnosed, untreated, and underreported. The disease adds significant cost and burden to the U.S. healthcare system with estimates for medical treatment and hospital stays associated with CDAD reaching as much as \$3.8 billion every year.

Optimer has taken a leadership position in driving a better understanding of the disease as CDAD is not as well characterized as some other hospital infections. Analysis of existing data sets reveals that mortality, hospital length of stay and average cost per CDAD episode can vary depending on patient type and complications. For example, a comparison of cancer patients with CDAD to cancer patients without CDAD reveals the following key differences:

- Cancer patients with CDAD have a higher mortality rate than cancer patients without CDAD (10.4% vs. 4.5%).
- Cancer patients with CDAD on average have longer length of stay in the hospital than cancer patients without CDAD (10.9 days vs. 5.5 days).
- Cancer patients with CDAD have a higher average cost per episode than cancer patients without CDAD (\$88,300 vs. \$41,896).

(Optimer analysis, Healthcare Cost and Utilization Project, 2011)

#### Morgan Stanley Global Healthcare Conference Webcast

A live audio webcast of Optimer's discussion at the Morgan Stanley Global Healthcare Conference will be accessible on the Investors page of the Company's website at [www.optimerpharma.com](http://www.optimerpharma.com). A replay will be available at the same location for 30 days following the meeting.

#### Important Safety Information for DIFICID

- DIFICID should not be used for systemic infections
- Only use DIFICID for infection proven or strongly suspected to be caused by *C. difficile*. Prescribing DIFICID in the absence of a proven or strongly suspected *C. difficile* infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria
- The most common adverse reactions are nausea (11%), vomiting (7%), abdominal pain (6%), gastrointestinal hemorrhage (4%), anemia (2%), and neutropenia (2%)

For full prescribing information for DIFICID, please call 1-855-DIFICID (855-343-4243) or visit [www.dificid.com](http://www.dificid.com)

#### About CDAD

*Clostridium difficile*-associated diarrhea (CDAD) has become a significant medical problem in hospitals, long-term care facilities and in the community. CDAD 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 CDAD from the use of broad-spectrum antibiotics that disrupt normal gastrointestinal (gut) flora, possibly allowing *C. difficile* bacteria to flourish. Older patients in particular are at risk for CDAD, potentially because of a weakened

immune system or the presence of underlying disease. Approximately two-thirds of CDAD patients are 65 years of age or older.

Current estimates suggest CDAD may affect more than 700,000 people in the U.S. each year, though the incidence may be higher as many cases are believed to be undiagnosed, untreated and underreported. The disease adds significant costs and burden to the U.S. healthcare system with estimates for medical treatment and hospital stays associated with CDAD reaching as much as \$3.8 billion every year. Historically, approximately 20% to 30% of CDAD patients who initially respond to treatment experience a clinical recurrence.

## **About Optimer**

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 developed and commercialized DIFICID™ (fidaxomicin) tablets, an FDA approved antibacterial drug for the treatment of adults 18 years of age and older with *Clostridium difficile*-associated diarrhea (CDAD). Optimer has filed a marketing authorization application with the European Medicines Agency for fidaxomicin. Optimer's clinical pipeline includes Pruvel™, a product in the fluoroquinolone class of antibiotics that has completed Phase 3 trials 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 statements related to the impact of Optimer's commercial efforts on sales and adoption of DIFICID, projections regarding the results and trends of the DIFICID launch, Optimer's goal of securing broad patient access for DIFICID, the number and timing of hospital formulary reviews and decisions, anticipated outreach activities to physicians through medical education and the incidence and costs of CDAD. Words such as "believes," "would," "anticipates," "plans," "expects," "may," "intend," "will" 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. These forward-looking statements are based on management's expectations on the date of this release. 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: Optimer's ability to continue driving adoption and use of DIFICID, whether healthcare professionals will prescribe DIFICID, whether DIFICID will receive or continue to receive reimbursement coverage from healthcare payers and government agencies, the extent to which DIFICID will be accepted on hospital formularies and potential delays in formulary decisions, Optimer's ability to successfully coordinate commercialization efforts with Cubist Pharmaceuticals under its co-promotion agreement, whether Optimer will be able to realize expected benefits under its co-promotion agreement with Cubist, the fact that past results may not be predictive of future results of performance, the possibility of alternative means of preventing or treating DIFICID impacting adoption and sales of DIFICID, Optimer's ability, through its third party manufacturers and logistics providers, to maintain a sufficient supply of DIFICID to meet demand, and other risks detailed in Optimer's filings with the Securities and Exchange Commission. Forward-looking statements speak only as of the date of this release, and Optimer undertakes no obligation to update or revise these statements, except as may be required by law.

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