



# Biocon Limited and Optimer Pharmaceuticals Announce Manufacturing and Supply Agreement for Fidaxomicin

Bangalore, May 24, 2010 – Biocon Limited (NSE: BIOCON), one of India's premier biotechnology companies and a global provider of manufacturing services and Optimer Pharmaceuticals, Inc. (NASDAQ:OPTR) a biopharmaceutical company focused on the treatment of serious infections such as Clostridium difficile infection (CDI), , announced today that they have entered into a long-term supply agreement for the commercial manufacturing of the active pharmaceutical ingredient fidaxomicin, Optimer's lead product candidate for the treatment of CDI.

"This long-term agreement with a world-class manufacturing expert such as Biocon is an important step in establishing a stable supply of fidaxomicin in the event it is approved," said Pedro Lichtinger, President and CEO of Optimer. "For the past five years, Biocon has been an important partner in our fidaxomicin development program and we look forward to continuing the relationship."

Kiran Mazumdar Shaw, CMD Biocon Group, added "Our partnership with Optimer is another wonderful recognition of Biocon's capabilities as an R&D partner as well as an acknowledgement of our global manufacturing facilities. The close research and development partnership over the last five years has been an enriching learning experience from a world class team for all the Biocon staffers working on this project."

Biocon's expertise in fermentation technology and the team's prior analytical development work with fidaxomicin made Biocon the most suited manufacturer for Optimer's product requirements.

CDI is caused by Clostridium difficile a spore-forming bacterium that can cause serious infection of the colon in humans by multiplying and producing toxins resulting in inflammation, severe diarrhea and, in serious cases, death. The primary risk factor for the development of CDI is the use of broad-spectrum antibiotics, as they can disrupt normal gastrointestinal flora, promoting C. difficile overgrowth. C. difficile typically affects older or severely ill patients who are hospital inpatients or residents of long-term-care facilities.

The Centers for Disease Control and Prevention (CDC) estimates that CDI affects nearly 500,000 people in the U.S. annually. Currently underreported and under-diagnosed, the CDC recognizes CDI as an unmet medical need and an emerging global public health crisis. In 2005, the U.S. Agency for Healthcare Research and Quality reported 28,600 deaths from CDI. Highly virulent strains of C. difficile bacteria have been identified in virtually every country, including the U.S., Canada, the Netherlands, France, UK, Switzerland, and Japan.

### **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. Optimer has successfully completed two Phase 3 trials showing superiority in global cure rates (defined as cure with no recurrence within four weeks of completing therapy) as well as a reduction in recurrences of up to 50% when compared with Vancomycin, the only FDA approved product for CDI. Optimer expects to submit an NDA in the second half of the year.

# **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™ 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.

#### **About Biocon Limited**

Established in 1978, Biocon Limited (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013), is one of India's largest biotechnology companies. The Group, promoted by Ms. Kiran Mazumdar-Shaw, is a fully-integrated, innovation-driven healthcare enterprise with strategic focus on biopharmaceuticals and research services. Biocon's value chain traverses the entire length of discovery, development and commercialization of novel therapeutics. With successful initiatives in clinical development, bio-processing and global marketing, Biocon delivers products and solutions to partners and customers in approximately 75 countries across the globe. Many of these products have USFDA and EMEA acceptance. Biocon's robust product offering includes the world's first recombinant human insulin, INSUGEN and India's first indigenously produced monoclonal antibody BIOMAb-EGFR(TM). For more information, visit www.biocon.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 and Optimer's development plans. Words such as "believes," "anticipates," "plans," "expects," "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 or Biocon's 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 or Biocon's respective businesses including, without limitation, risks relating to: the timing, progress and likelihood of success of Biocon's manufacturing and scale-up efforts related to fidaxomicin and the timing, preparation and results of applications for marketing approval for fidaxomicin, and other risks detailed in Optimer's filings with the Securities and Exchange Commission.