

## **Astellas enters into partnership with Optimer on life-saving antibiotic fidaxomicin**

### **Product already filed with European Medicines Agency**

Staines, London Feb 7<sup>th</sup> 2011 – Astellas Pharma Europe Ltd. announced today that it has entered into an exclusive collaboration and license agreement with Optimer Pharmaceuticals Inc., San Diego for the development and commercialisation of fidaxomicin, an investigational antibiotic for *Clostridium difficile* infection (CDI) in Europe and certain other countries in the Middle East, Africa and the Commonwealth of Independent States (CIS).

Fidaxomicin is an orally administered, macrocyclic antibiotic with a new mechanism and narrow spectrum of action. This novel medicine is currently being reviewed for market authorisation in both the US and Europe for the treatment of CDI and reduction in the risk of recurrence when used for treatment of initial CDI. Optimer filed the marketing authorisation application (MAA) for fidaxomicin with the European Medicines Agency (EMA) on 29 July 2010, and the EMA accepted it for review as treatment for patients with *Clostridium difficile* infection (CDI) and for the recurrences of CDI in the EU. Additionally, although Astellas will not have marketing rights to fidaxomicin in the United States, Optimer filed a New Drug Application (NDA) for the product with the Food and Drug Administration (FDA) late last year, and the FDA has accepted that application and has granted the company's request for a six-month Priority Review, assigning a Prescription Drug User Fee Act goal date of 30 May 2011.

To date, two phase III clinical studies have been completed showing that fidaxomicin successfully met the primary endpoint of non-inferiority when comparing the treatment to oral vancomycin in achieving clinical cure – defined as patients requiring no further CDI therapy two days after completion of study medication, as determined by the investigator. Furthermore in both trials, fidaxomicin was statistically superior to vancomycin in global cure and in reducing recurrences of CDI by up to 47%. This evidence is of great significance given that the medical community has yet to find a successful and reliable treatment for recurrent CDI.

“We believe the strengths of Astellas’ world-class anti-infective business capabilities including established relationships with payers and hospitals in Europe and other markets, combined with Optimer’s novel therapeutic for CDI, represents the most effective way to address a serious, unmet health need,” said Mr. Masao Yoshida, President and CEO of Astellas Pharma Europe Ltd. “We look forward to bringing fidaxomicin to these markets to help patients and providers address this serious life threatening disease.”

Under the terms of the agreement, Astellas is granted exclusive rights to develop and commercialise fidaxomicin in Europe and certain other countries in the Middle East, Africa and the Commonwealth of Independent States (CIS). Astellas will pay €50 million up front and approximately €115 million in milestone payments on achievement of pre-specified development and sales milestones.

“We expect the Astellas collaboration will help Optimer realize the full potential of fidaxomicin and will help position this medication in these countries as the first line of treatment, both for treating CDI and reducing recurrences,” said Pedro Lichtinger, Optimer’s President and CEO. “CDI poses a significant cost burden on the healthcare system and we believe, if approved, fidaxomicin will provide a cost-savings opportunity for hospitals and payers, especially when used in populations at risk of recurrence such as the elderly, patients with a prior episode, those taking concomitant antibiotics, immuno-compromised patients or those with renal impairment.”

*Clostridium difficile*, commonly referred to as “*C.difficile*” or “*C.diff*” is a bacteria that causes serious illness, through infecting the inner lining of the colon and producing toxins that cause inflammation of the colon, severe diarrhoea and in the most serious cases, death. Patients typically develop CDI following the use of broad-spectrum antibiotics that disrupt the normal gastrointestinal (gut) flora, thus allowing *Clostridium difficile* bacteria to flourish and produce harmful side effects.

*Clostridium difficile* in Europe is associated with significant health and economic burden, and incidence of this serious disease has been increasing across Europe over the last 10 years. Treatments that provide both a high success rate and low infection recurrence rate are, therefore, welcomed in order to combat this illness.

Astellas already has an ongoing commitment to combating infectious disease through the worldwide launch of its injectable antifungal, the echinocandin Mycamine® (micafungin), and in September 2009, the launch in the United States of Vibativ® (telavancin) an injectable antibacterial for the treatment of adults with infections caused by gram-positive pathogens including MRSA. Astellas is currently liaising with the European regulatory authorities to license Vibativ for the treatment of adults with Nosocomial Pneumonia and complicated Skin and Soft Tissue Infections (cSSTIs). In addition, Astellas is continuing to develop its franchise in infectious disease with the development of isavuconazole, an antifungal for the treatment of invasive fungal infections, including Aspergillosis. The compound is currently in Phase III trials. This new partnership is an important step to further expand our business and to reinforce our franchise in infectious diseases.

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**About Astellas Pharma Europe Ltd:**

Astellas Pharma Europe Ltd., located in the UK, is a European subsidiary of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. The organisation is committed to becoming a global company by combining outstanding R&D and marketing capabilities

and continuing to grow in the world pharmaceutical market. Astellas Pharma Europe Ltd. is responsible for 21 affiliate offices located across Europe, the Middle East and Africa, an R&D site and three manufacturing plants. The company employs approximately 3,900 staff across these regions. For more information about Astellas Pharma Europe, please visit [www.astellas.eu](http://www.astellas.eu).

**About Optimer Pharmaceuticals:**

Optimer Pharmaceuticals, Inc. is a biopharmaceutical company focused on discovering, developing and commercializing hospital specialty products to treat serious infections and address unmet medical needs. Optimer has two anti-infective product candidates in development, fidaxomicin and Pruvel™ (prulifloxacin). Fidaxomicin is a narrow spectrum antibiotic being developed for the treatment of *Clostridium difficile* infection. The FDA granted Optimer's request for a six-month Priority Review of fidaxomicin, and has assigned a Prescription Drug User Fee Act (PDUFA) goal date of May 30, 2011. Optimer has also filed a MAA with the European Medicines Agency (EMA) for fidaxomicin. 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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