

FOR IMMEDIATE RELEASE

European Commission Grants Marketing Authorisation for Astellas Pharma Europe Ltd.'s DIFICLIR™ for use in the EU

STAINES, UK, 12 December 2011 – Astellas Pharma Europe Ltd. a European subsidiary of Tokyo-based Astellas Pharma Inc. (Tokyo: 4503) and Optimer Pharmaceuticals, Inc. (NASDAQ: OPTR) announced today that the European Commission has granted a marketing authorisation for DIFICLIR™ (fidaxomicin) tablets for the treatment of adults with *Clostridium difficile* infections (CDI), also known as *C. difficile*-associated diarrhoea (CDAD), in the European Union.¹

“Treatment for CDI has changed little in the past 20 years, even though the disease has a major impact on patients’ health and quality of life and is potentially fatal. The EU approval of DIFICLIR, a novel macrocyclic antibiotic that specifically targets *C. difficile* bacteria, is therefore an important advance for patients suffering from CDI,” said Ken Jones, President and CEO of Astellas Pharma Europe Ltd.

CDI is one of the most common causes of antibiotic-associated diarrhoea.² Severe cases can lead to bowel surgery and even death.² CDI is a significant problem in hospitals, nursing homes and other long-term care facilities.³ Recurrence of CDI occurs in up to 25% of patients within 30 days of initial treatment with current therapies.^{4,5,6}

The EU approval of DIFICLIR was based on two Phase III clinical studies comparing the efficacy and safety of 400mg/day oral DIFICLIR with 500mg/day oral vancomycin (the only approved treatment for CDI) for a treatment period of 10 days in adults with CDI in Europe and North America.^{6,7} The proportion of subjects in whom clinical cure* was achieved were similar for the two treatments, and hence DIFICLIR met its primary endpoint of non-inferiority to vancomycin.^{6,7} The results also showed potential advantages of DIFICLIR over vancomycin. DIFICLIR significantly reduced the rate of CDI recurrence as compared with vancomycin, with patients treated with DIFICLIR significantly more likely than those receiving vancomycin to experience diarrhoea resolution without recurrence within 30 days of therapy completion.^{6,7} In addition, DIFICLIR causes minimal disruption of the normal intestinal flora⁸ and few systemic adverse events compared with vancomycin.^{6,7}

“*The high rate of disease recurrence is the greatest limitation of current treatments for CDI,*” said Professor Mark Wilcox, Professor of Medical Microbiology, Leeds Teaching Hospitals & University of Leeds. “*The significant reduction in disease recurrence by DIFICLIR compared with vancomycin is a key step to reducing the morbidity associated with CDI, and this new treatment option is a welcome addition that has the potential to improve the patient experience*”.

DIFICLIR, which is known as DIFICID™ in the United States (US), was discovered and developed by Optimer, and was approved by the US Food and Drug Administration in May 2011 for the treatment of CDAD⁹ in adults aged 18 years and older.¹⁰ Astellas Pharma Europe Ltd. is Optimer's exclusive licensee for the development and commercialisation of DIFICLIR in Europe and additional countries in the Middle East, Africa and the Commonwealth of Independent States.

-ENDS-

*Please note: clinical cure was defined in these two clinical trials as patients requiring no further CDI therapy two days after completion of study medication, as determined by the investigator.

NOTES TO EDITORS:

About *Clostridium Difficile* Infection (CDI)

CDI is a serious illness resulting from infection of the internal lining of the colon by *C. difficile* bacteria. The bacteria produce toxins that cause inflammation of the colon, diarrhoea and, in some cases, death.² Patients typically develop CDI after the use of broad-spectrum antibiotics that disrupt normal gastrointestinal flora, allowing *C. difficile* bacteria to flourish.² The risk of CDI and disease recurrence is particularly high in patients aged 65 years and older.¹¹ CDI results in substantial costs to healthcare systems, in particular because of extended hospitalisation.¹²

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 4,200 staff across these regions. For more information about Astellas Pharma Europe, please visit www.astellas.eu.

About Optimer Pharmaceuticals, Inc.:

Optimer Pharmaceuticals, Inc. is a biopharmaceutical company focused on discovering, developing and commercialising hospital specialty products to treat serious infections and address unmet medical needs. Additional information can be found at <http://www.optimerpharma.com>.

#####

For more information:

Katy Compton Bishop

Ruder Finn

Tel: 020 7462 8922

Email : kcompton-bishop@ruderfinn.co.uk

Mindy Dooa

Astellas Pharma Europe Ltd.,

Tel : 01784 419 444

Email : mindy.dooa@eu.astellas.com

References

- ¹ European Commission. Community register of medicinal products for human use. <http://ec.europa.eu/health/documents/community-register/html/h733.htm>. Last accessed 12 December 2011.
- ² Ananthkrishnan AN. *Clostridium difficile* infection: epidemiology, risk factors and management. *Nat Rev Gastroenterol Hepatol* 2011;8:17–26.
- ³ Simor AE, et al. *Clostridium difficile* in Long-term-care facilities for the elderly. *Infect Control Hosp Epidemiol.* 2002;23:696-703.
- ⁴ Bouza E, et al. Results of a phase III trial comparing tolevamer, vancomycin and metronidazole in patients with *Clostridium difficile*-associated diarrhoea. *Clin Micro Infect.* 2008;14(Suppl 7):S103-4.
- ⁵ Lowy I, et al. Treatment with Monoclonal Antibodies against *Clostridium difficile* Toxins. *NEJM.* 2010;362;3:197-205.
- ⁶ Louie TJ, et al. Fidaxomicin versus vancomycin for *Clostridium difficile* infection. *N Engl J Med* 2011;364:422–31.
- ⁷ Crook D, et al. Randomized clinical trial (RCT) in *Clostridium difficile* infection (CDI) confirms equivalent cure rate and lower recurrence rate of fidaxomicin (FDX) versus vancomycin (VCN). 20th Annual European Congress of Clinical Microbiology and Infectious Diseases (ECCMID); Vienna, Austria, 10-13 April 2010; Abstract LB2401.
- ⁸ Tannock GW, et al. A new macrocyclic antibiotic, fidaxomicin (OPT-80), causes less alteration to the bowel microbiota of *Clostridium difficile*-infected patients than does vancomycin. *Microbiology* 2010;156:3354–9.
- ⁹ Food and Drug Administration. FDA approves treatment for *Clostridium difficile* infection [Internet]. [updated May 27 2011; cited September 16 2011]. Available from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm257024.htm>.
- ¹⁰ DIFICID US Prescribing Information. Optimer Pharmaceuticals, Inc. 2011.
- ¹¹ Pepin J, et al. Increasing risk of relapse after treatment of *Clostridium difficile* colitis in Quebec, Canada. *Clin Infect Dis* 2005;40:1591–7.
- ¹² Ghantaji SS, et al. Economic healthcare costs of *Clostridium difficile* infection: a systematic review. *J Hosp Infect* 2010;74:309–18.