

Astellas Pharma: DIFICLIR™, a Novel Treatment for *Clostridium difficile* infections (CDI), Launched in Europe

Tokyo, Japan, June 11, 2012 - [Astellas Pharma Inc.](#) (Tokyo:4503, “Astellas”) today announced that Astellas Pharma Europe Ltd. (“Astellas Europe”), a European subsidiary of Astellas, launched DIFICLIR™ (generic name: fidaxomicin) tablets, into the European market.

In February 2011, Astellas was granted exclusive rights to develop and commercialize DIFICLIR in Europe and certain other countries in the Middle East, Africa and the Commonwealth of Independent States (CIS) (“Territory”) by Optimer Pharmaceuticals, Inc. (“Optimer”). The European Commission granted Marketing Authorization for DIFICLIR tablets for the treatment of adults with *Clostridium difficile* infections (CDI), also known as *Clostridium difficile* – associated diarrhoea, in December 2011.

DIFICLIR is an orally administered, macrocyclic antibiotic with a targeted spectrum of action that was developed by Optimer Pharmaceuticals. In clinical trials, DIFICLIR met its primary endpoint of non-inferiority to vancomycin.¹ DIFICLIR also significantly reduced the recurrence of CDI in patients by 47% relative to vancomycin (planned secondary endpoint, 13.0% versus 24.6%, p=0.0001).^{1,2,3} Recurrence of CDI occurs in up to 25% of patients within 30 days of initial treatment with current therapies.¹ The European Society of Clinical Microbiology and Infectious Diseases (ESCMID) has identified recurrence as being the most important problem in the treatment of CDI.⁴

Astellas is due to pay €50 million in milestones, comprised of €40 million due 6 months after MAA approval and a separate €10 million due on the first launch of a product in the Territory. These milestone payments of €50 million have been reflected in Astellas’ current fiscal year (from April 1, 2012 to March 31, 2013) financial forecast.

Astellas expects to provide a new therapeutic option with CDI patients, and further fortify its infectious disease franchise.

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For inquiries or additional information

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¹ Louie TJ, *et al.* Fidaxomicin versus vancomycin for *Clostridium difficile* infection. *N Engl J Med.* 2011;364:422–31.

² Cornely A, *et al.* Fidaxomicin versus vancomycin for infection with *Clostridium difficile* in Europe, Canada, and the USA: a double-blind, non-inferiority, randomised controlled trial. *Lancet Infect Diseases.* doi:10.1016/S1473-3099(11)70374-7

³ Mullane KM *et al.* Fidaxomicin: first-in-class macrocyclic antibiotic. *Expert Rev. Anti Infect. Ther.*

⁴ Bauer MP, *et al.* European Society of Clinical Microbiology and Infectious Disease (ESCMID): treatment guidance document for *Clostridium difficile*-infection (CDI). *Clin Microbiol Infect.* 2009;15:1067-79.