

Press Release

Astellas Announces Launch of Dafclir[®] Tablets for the Treatment of Infectious Enteritis Caused by *Clostridium difficile* in Japan

TOKYO, September 18, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) today announced that it has launched Dafclir[®] Tablets 200 mg (generic name: fidaxomicin, “Dafclir[®]”) for the treatment of infectious enteritis (including pseudomembranous colitis¹) (susceptible strains: fidaxomicin susceptible *Clostridium difficile* (CD)²) in Japan.

Dafclir[®] is an oral macrocyclic antimicrobial agent³ with a new mechanism of action and a selective antibacterial spectrum licensed from Merck & Co., Inc. Kenilworth, N.J., U.S.A., known as MSD outside the U.S. and Canada (“Merck”). Astellas has developed the product in Japan based on an exclusive development and marketing agreement with Merck. In addition, our subsidiary Astellas Pharma Europe Ltd. has acquired exclusive license for the development and commercialization in Europe, where it is already being marketed as a CD infection treatment, and additional countries in the Middle East, Africa and the Commonwealth of Independent States (CIS)⁴.

CD, a bacterium that infects large intestine and produces toxins, causes nosocomial infections and antibacterial agent-associated colitis worldwide. Infection and proliferation result in colitis and severe diarrhea and in the most serious cases death. As difficulty in treatment of infectious enteritis caused by CD with the currently available pharmaceutical products, mainly due to the recurrence, has been reported in Japan, new treatment options have been needed. Besides its potent antibacterial activity against CD, due to its narrow antibacterial spectrum, Dafclir[®] minimally disrupts the balance of intestinal flora, and it inhibits spore formation⁵.

Astellas will further contribute to patients who are suffering from infectious enteritis caused by CD in Japan by launching Dafclir[®] as a new therapeutic option.

Astellas reflected the impact from this launch in its financial forecasts of the current fiscal year ending March 31, 2019.

Product overview

Trade name	Dafclir® Tablets
Generic name	Fidaxomicin
Indication	<Susceptible strains > fidaxomicin susceptible <i>Clostridium difficile</i> <Indication> Infectious enteritis (including pseudomembranous colitis)
Dosage and administration	Normally to adult, one tablet (200 mg as fidaxomicin) twice daily orally
NHI drug price	Dafclir® Tablets 200 mg (one 200 mg tablet): 3,943.80 yen
Date of approval	July 2, 2018
Date of NHI drug price listing	August 29, 2018
Date of Launch	September 18, 2018

Product photo



- (1) Pseudomembranous colitis: the large intestines of healthy individuals have a good balance of various types of bacteria that helps maintain health. However, when taking antibiotics, the normal balance of intestinal bacteria may be disrupted and some types of bacteria may proliferate abnormally and cause inflammation. Pseudomembranous colitis is a disease in which small circular membranes (pseudomembranes) appear in the large intestine wall and in most cases it is reportedly due to CD.
- (2) *Clostridium difficile*: *Clostridium difficile* is a bacterium that infects the large intestine and produces toxins. Infection and proliferation result in colitis and severe diarrhea and in the most serious cases death. In an environment in which intestinal bacteria growth is normal, when infection with *Clostridium difficile* occurs, its growth will be inhibited. However, due to antibacterial agents with a broad antibacterial spectrum taken to treat other diseases, the balance may be lost resulting in abnormal growth of *Clostridium difficile*. *Clostridium difficile* infection still remains an area with high unmet medical needs because there are few effective treatments and the recurrence rate is high.
- (3) Macrocyclic antimicrobial agent: a category of antibacterial agents (antibiotics) defined by chemical structure.
- (4) Commonwealth of Independent States (CIS): loose confederation of independent states consisting of 11 of the republics of the former Union of Soviet Socialist Republics.
- (5) Spore formation: When their living environment deteriorates, some bacteria form spores in order to survive. With strong resistance to heat, dryness and disinfectants, spores can survive/live for a long time in severe environments. In hospitals, they can be propagated by the hands of medical staff or medical equipment and cause nosocomial infections.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at <https://www.astellas.com/en>

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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