Press Release

Astellas Submits Application for Approval of fidaxomicin for the Treatment of Infectious Enteritis Caused by *Clostridium difficile* in Japan

Tokyo, July 31, 2017 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") today announced that it has submitted an application for marketing approval of fidaxomicin (generic name) for the treatment of infectious enteritis (including pseudomembranous colitis[1]) (susceptible strains: fidaxomicin susceptible *Clostridium difficile*[2]).

Fidaxomicin is an oral macrocyclic antimicrobial agent[3] with a new mechanism of action and a selective antibacterial spectrum licensed from Merck & Co., Inc. ("Merck"). It is already being marketed in the United States as a *Clostridium difficile* ("CD") associated diarrhea and Europe as a CD infection treatment. 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, 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 has been reported with the treatments of infectious enteritis caused by CD which has already been approved in Japan, mainly due to recurrence, new treatment options have been needed. Besides its potent antibacterial activity against CD, due to its narrow antibacterial spectrum, it minimally disrupts the balance of intestinal flora, and it inhibits spore formation[5].

Astellas expects to contribute to the advancement of the treatments of infectious enteritis caused by CD in Japan by providing fidaxomicin as a new therapeutic option.

Submission of the application for marketing approval has no impact on the financial results for the fiscal year 2017 ending March 31, 2018.

(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 is considered to be a great unmet medical need 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. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. 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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