

## Press Release

### **Astellas Transfers DIFICLIR™ in Europe, Middle East, Africa and selected CIS to Tillotts Pharma**

**TOKYO, November 27, 2020** - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas” ) today announced that the subsidiary Astellas Pharma Europe Ltd. (“Astellas Europe”) and Tillotts Pharma AG (“Tillotts”) have entered into an Asset Purchase Agreement, under which Astellas Europe will transfer its marketing authorizations for “DIFICLIR™ (generic name: fidaxomicin) tablets” for Clostridium difficile (CD)<sup>1</sup> infections in Europe, Middle East, Africa and selected Commonwealth of Independent States (CIS)<sup>2</sup> to Tillotts.

After the closing of the agreement and according to transitional arrangements, Tillotts will take over DIFICLIR™ from Astellas and manufacture and sell it in Europe, Middle East, Africa and selected CIS. Astellas will continue to work with Tillotts Pharma to promptly transfer its marketing authorizations to ensure stable delivery of this product to patients.

DIFICLIR™ is a unique narrow-spectrum macrocyclic anti-bacterial agent<sup>3</sup> available as film-coated tablets and granules licensed from a subsidiary of Merck & Co., Inc. Kenilworth, N.J., U.S.A., known as MSD outside the U.S. and Canada. Astellas Europe has been selling DIFICLIR™ in Europe since 2012 and expanded our sales area to the Middle East and Africa. Astellas will continue to sell Dafclir® tablets in Japan, where it has the marketing authorization for the treatment of infectious enteritis (including pseudomembranous colitis<sup>4</sup>) (susceptible strains: fidaxomicin susceptible CD).

#### **(1) Purpose of Asset Purchase Agreement**

The agreement is a part of Astellas’ ongoing efforts to improve the quality and efficiency of operations so as to accommodate the rapidly changing business environment and achieve sustainable growth. Astellas will continue to strengthen our business presence in Europe, Middle East, Africa and CIS through optimization of resource allocation.

#### **(2) Financial Terms of Asset Purchase Agreement**

€109 million

#### **(3) Schedule of Asset Purchase Agreement**

November 24, 2020: Signing of the Asset Purchase Agreement

## Third quarter of the fiscal year 2020: Closing of the Asset Purchase Agreement (tentative)

After closing of the agreement, marketing authorization of the product will be transferred in each country.

### **(4) Sales of the DIFICLIR™ in Europe, Middle East, Africa and selected CIS** €28 million (fiscal year ended March 31, 2020)

The impact from this transaction is not reflected in Astellas' consolidated financial forecasts for the fiscal year ending March 31, 2021. Since part of the consideration for the transfer is recognized as revenue during the current fiscal year, we expect a positive impact on revenue and operating profit.

- (1) *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.
- (2) Commonwealth of Independent States (CIS): loose confederation of independent states consisting of the former Union of Soviet Socialist Republics.
- (3) Macrocyclic antimicrobial agent: a category of antibacterial agents (antibiotics) defined by chemical structure.
- (4) 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.

#### **About Astellas**

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands 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>.

**About Tillotts**

Tillotts Pharma AG, part of the Japanese Zeria Group, is a fast-growing specialty pharma company with over 300 employees in Switzerland and abroad. Tillotts is dedicated to the development, in/out-licensing and commercialization of innovative pharmaceutical products for the digestive system. Tillotts successfully markets its own products for the treatment of IBD as well as in-licensed products, in around 65 countries through its affiliates within Europe and a network of gastroenterology-focused partners throughout the world.

**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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