

Press Release

Astellas Confirms Unfavorable District Court Decision in LEXISCAN[®] 0.4mg/mL U.S. Patent Trial

TOKYO, May 20, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) today confirmed the U.S. District Court for the District of Delaware ruling that all asserted claims of the 8,106,183; 8,524,883; and RE47301 patents for LEXISCAN[®] (regadenoson injection) 0.4 mg/mL are not infringed. The patent infringement trial involved one Abbreviated New Drug Application (ANDA) filer, Hospira, Inc. Hospira is requesting permission from FDA to manufacture and commercialize a generic LEXISCAN[®] product before expiration of the LEXISCAN[®] patents. Astellas plans to appeal the decision and to take legal action to prevent Hospira from launching generic LEXISCAN[®] pending resolution of the appeal.

Astellas is reviewing the potential financial impacts of this district court decision for the fiscal year ending March 31, 2023.

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>.

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.

###

Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Advocacy & Relations
+81-3-3244-3201