



Press Release

Astellas Confirms District Court Decision for an Interim Injunction Against Hospira for LEXISCAN® 0.4mg/mL

TOKYO, September 26, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) confirms the U.S. District Court for the District of Delaware’s order granting an interim injunction enjoining Hospira from launching its generic version of LEXISCAN® until October 5, 2022. The District Court, however, denied Astellas’ request for a Preliminary Injunction while Astellas’ appeal is pending with the Court of Appeals for the Federal Circuit (CAFC). Astellas is filing a Motion for Preliminary Injunction with the CAFC to prevent Hospira from launching generic LEXISCAN® until the CAFC resolves Astellas’ pending appeal of the district court decision.

On May 19, 2022, the U.S. District Court for the District of Delaware issued its decision that all of the 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. Astellas appealed this decision with the CAFC on June 1, 2022.

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 at 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 concerning 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 considering the information currently available to it and involve known and unknown risks and uncertainties. Several 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) included in this press release is not intended to constitute an advertisement or medical advice.

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