

Press Release

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

TOKYO, January 4, 2023 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) confirmed the Court of Appeals for the Federal Circuit (CAFC) affirmed the earlier decision by the U.S. District Court for the District of Delaware that all asserted claims of the patents for LEXISCAN[®] (regadenoson injection) 0.4 mg/mL are not infringed by Hospira, Inc.

On December 6, 2022, the CAFC heard oral arguments, and the Temporary Stay preventing Hospira, Inc. from launching its generic expired. The CAFC also denied our motion for an Injunction pending appeal. The CAFC issued its decision affirming the earlier District Court decision on December 30, 2022.

Astellas is evaluating its legal options. We are also reviewing the potential financial impact for the fiscal year ending March 31, 2023.

For more information, please see [the press release issued on May 20, 2022](#), and [the press release issued on September 26, 2022](#).

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 which 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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