

Astellas Confirms Unfavorable District Court Decision Concerning its Motion for a Preliminary Injunction Against Lupin and Zydus Generic Versions of Myrbetriq™

TOKYO, April 22, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, “Astellas”) confirms the U.S. District Court for the District of Delaware has filed a Report and Recommendation that recommends denying Astellas’ motion for a preliminary injunction that sought to enjoin Lupin and Zydus from launching their generic versions of Myrbetriq™ at risk prior to the conclusion of pending patent litigation involving Astellas’ U.S. Patent No. 11,707,451 (“the ‘451 patent”). Astellas plans to file objections to the Report. In July 2023, Astellas filed this lawsuit in the U.S. District Court for the District of Delaware asserting that Zydus’ and Lupin’s generic versions of Myrbetriq™ infringe the ‘451 patent.

Astellas also has separate patent litigation against Zydus and Lupin in which Astellas asserts that Zydus’ and Lupin’s versions of Myrbetriq™ infringe Astellas’ U.S. Patent No. 10,842,780. That case is currently pending at the Court of Appeals for the Federal Circuit (CAFC).

Astellas is reviewing the impact that an at risk launch would have in its financial forecast of the fiscal year ending March 31, 2025 that is scheduled to be disclosed on April 25, 2024.

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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