

## Press Release

# Astellas Confirms Unfavorable District Court Decision in Myrbetriq<sup>®</sup> U.S. Patent Trial

**TOKYO, June 12, 2023** – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") confirmed the U.S. District Court for the District of Delaware issued a decision on June 9 finding U.S. Patent No. 10,842,780 (the "'780 Patent", which expires in March 2030) invalid. The '780 Patent covers extended-release drug formulations of mirabegron, including Myrbetriq<sup>®</sup>. This lawsuit was filed by Astellas in the U.S. District Court for the District of Delaware requesting a judgement that certain generic pharmaceutical companies' proposed generic versions of Myrbetriq<sup>®</sup> infringe the '780 Patent.

Astellas plans to appeal the decision to the United States Court of Appeals for the Federal Circuit (CAFC).

Patents covering crystal forms and methods of using mirabegron, which were the subject of earlier litigation, remain valid and expire in May 2024. Astellas does not anticipate the immediate launch of generic mirabegron.

This decision will have no impact on the financial forecasts of the current fiscal year ending March 31, 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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