

Astellas Filed Lawsuit against Patent Infringement of Myrbetriq[®] in the United States

Tokyo, Japan, October 7, 2016 - Astellas Pharma Inc. (TSE: 4503; President and CEO: Yoshihiko Hatanaka, “Astellas”) and its subsidiaries jointly filed a lawsuit against Actavis Elizabeth LLC and its affiliates (“Actavis”), who filed an abbreviated new drug application (ANDA) for a generic version of Astellas’ mirabegron (generic name) product sold under the trademark Myrbetriq[®] in the United States. Astellas’ mirabegron product is protected by patents in the U.S. that cover the active compound, itself, its use for overactive bladder and polymorphic forms of the compound.

This lawsuit was filed with the United States District Court for the District of Delaware on October 6, 2016 (EST) requesting, among other items, a judgment that Actavis has infringed the above patents and an order that the date of approval of Actavis’ ANDA not be earlier than the expiration of Astellas’ patents with respect to mirabegron, or any later date of exclusivity that Astellas is or becomes entitled to.

Mirabegron was invented by Astellas and has been marketed in more than 40 countries and areas since its commercial launch in Japan in 2011. In the U.S., Astellas Pharma US, Inc. has been marketing mirabegron since 2012 under the brand name Myrbetriq[®].

This lawsuit will not materially affect Astellas’ financial results of the current fiscal year ending March 31, 2017.

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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.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

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