Press Release

Astellas Received Approval for Solifenacin Oral Suspension for Pediatric Patients in Europe

Tokyo, March 9, 2018 - Astellas Pharma Inc. (President and CEO: Yoshihiko Hatanaka, “Astellas”) today announced that solifenacin succinate (generic name, “solifenacin”) oral suspension received approval in Europe for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 2 to 18 years. This approval was received in European 31 countries including the Netherlands which was the Reference Member State by Decentralized Procedure which is a type of Mutual Recognition.

NDO, in which a neurologic defect can impair the signaling between the bladder and the central nervous system and cause uncontrolled urination, is associated with certain neurological conditions, such as multiple sclerosis or a spinal injury. In children, a congenital neural tube defect[1], such as spina bifida[2], is the most common cause of NDO.[3]

The dosage form of solifenacin oral suspension was approved in 2015 for the use in adults with overactive bladder with symptoms of urgency, frequency, and urge incontinence based on bioequivalence with solifenacin tablets which was approved in Europe in 2004. Current approval is addition of a pediatric indication. The solifenacin oral suspension will be available for pediatric patients with NDO aged 2 to 18 years in a 1 mg/1 mL dose oral suspension. Solifenacin are being sold in more than 80 countries worldwide[4].

Astellas is pleased to deliver Solifenacin oral suspension to pediatric patients to further enhance its contributions to the treatment of NDO in the future.

The approval will have no impact on the consolidated financial forecasts for the fiscal year 2017 ending March 2018.

(1) Congenital neural tube defect: A birth defect results from a failure in closing of the neural tube during gastrulation, which causes congenital malformations of the spinal cord and brain.

(2) Spina bifida: A birth defect in which the vertebral column is open, often with spinal cord involvement.

(3) Dorsher, McIntosh, “Neurogenic Bladder,” Advances in Urology, 2012

(4) Only the tablets are being sold in Japan.

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 https://www.astellas.com/jp/en.

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.

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