Press Release

FDA Accepts for Priority Review the New Drug Application for mirabegron for Oral Suspension and Supplemental New Drug Application for Myrbetriq® (mirabegron) Tablets in Pediatric Patients

TOKYO, January 6, 2021 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") announced today that the U.S. Food and Drug Administration (FDA) accepted priority review for its New Drug Application (NDA) for mirabegron for oral suspension and its supplemental New Drug Application (sNDA) for Myrbetriq® (mirabegron) tablets for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged three years and older. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is March 28, 2021.

"These regulatory submissions mark an important step toward addressing the unmet treatment needs for children with neurogenic detrusor overactivity. Treatment options for children with neurogenic detrusor overactivity are limited," said Salim Mujais, M.D., senior vice president and head, Medical Specialties, Astellas. "Mirabegron has the potential to expand the repertoire of treatments available for these children, offering a favorable balance of efficacy and tolerability."

NDO is a neurological bladder dysfunction caused by nerve damage. Children with NDO may experience involuntary bladder contractions, which can lead to symptoms of urinary urgency, frequency and incontinence.[1] Spina bifida, a congenital spinal cord defect, is a common cause of NDO in children.[2]

The NDA and sNDA were based on findings from a Phase 3 pivotal study that evaluated the efficacy, safety, tolerability and pharmacokinetics of mirabegron in children and adolescents (aged 3 to <18 years) with NDO and using clean intermittent catheterization (ClinicalTrials.gov Identifier: NCT02751931).

Myrbetriq® tablets were initially approved in 2012 in the United States for the treatment of adults with overactive bladder with symptoms of urge urinary incontinence, urgency and urinary frequency.

USE OF MYRBETRIQ

Myrbetriq® (mirabegron) is a prescription medicine for adults that can be used alone or with solifenacin succinate to treat overactive bladder (OAB) with symptoms of urgency, frequency and leakage.

IMPORTANT SAFETY INFORMATION FOR MYRBETRIQ

Myrbetriq is not for everyone. Do not take Myrbetriq if you have an allergy to mirabegron or any ingredients in Myrbetriq. Myrbetriq may cause your blood pressure to increase or make your blood pressure worse if you have a history of high blood pressure. It is recommended that your doctor check your blood pressure while you are taking Myrbetriq. Myrbetriq may increase your chances of not being able to empty your bladder. Tell your doctor right away if you have trouble emptying your bladder or you have a weak urine stream.

Myrbetriq may cause allergic reactions that may be serious. If you experience swelling of the face, lips, throat or tongue, with or without difficulty breathing, stop taking Myrbetriq and tell your doctor right away.
Tell your doctor about all the medicines you take including medications for overactive bladder or other medicines such as thioridazine (Mellaril™ and Mellaril-S™), flecainide (Tambocor®), propafenone (Rythmol®), digoxin (Lanoxin®), or solifenacin succinate (VESIcare®). Myrbetriq may affect the way other medicines work, and other medicines may affect how Myrbetriq works.

Before taking Myrbetriq, tell your doctor if you have liver or kidney problems. The most common side effects of Myrbetriq include increased blood pressure, common cold symptoms (nasopharyngitis), dry mouth, flu symptoms, urinary tract infection, back pain, dizziness, joint pain, headache, constipation, sinus irritation, and inflammation of the bladder (cystitis).

The most common side effects of MYRBETRIQ, when used with solifenacin succinate, include dry mouth, urinary tract infection, constipation, and fast heartbeat.

Please refer to the solifenacin succinate Patient Product Information and complete Prescribing Information when taking in combination with Myrbetriq.

For further information, please talk to your healthcare professional and see accompanying Patient Product Information and complete Prescribing Information for Myrbetriq® (mirabegron).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1‑800‑FDA‑1088.

Please see accompanying complete Prescribing Information for Myrbetriq® (mirabegron).

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 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/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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References

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[2] UCSF Pediatric Urology. Spina bifida / myelomeningocele / neurogenic bladder. Available at: https://urology.ucsf.edu/sites/urology.ucsf.edu/files/uploaded-files/basic-page/spina_bifida_myelomeningocele_neurogenic_bladder_080615_0.pdf. Last accessed December 2020.