Press Release

Astellas Garners New Indication & New Product Formulation Approvals From U.S. FDA for Children with Neurogenic Detrusor Overactivity (NDO)

Myrbetriq® (Mirabegron Extended-Release Tablets) Approved for Pediatric Patients with NDO Aged Three Years and Older Weighing 35 kg or More

Myrbetriq® Granules (Mirabegron for Extended-Release Oral Suspension) Approved for Pediatric Patients with NDO Aged Three Years and Older

TOKYO, March 26, 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) approved Myrbetriq® (mirabegron extended-release tablets) for the treatment of NDO in pediatric patients aged three years and older who weigh 35 kg or more, and Myrbetriq® Granules (mirabegron for extended-release oral suspension) for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged three years and older. The FDA also granted pediatric exclusivity for Myrbetriq, resulting in an additional six month period of market exclusivity.

Myrbetriq and Myrbetriq Granules are first-in-class to now be FDA-approved for children with NDO. Treatment options for NDO have been limited or invasive, including scheduled toileting, catheterization, or surgery.[1] If left untreated, NDO can lead to the deterioration of urinary tract function at an early age.[2]

"With this latest approval, Astellas is bringing forward a new treatment option for children impacted by NDO, an especially vulnerable patient population with high unmet need," said Salim Mujais, M.D., senior vice president and head, Medical Specialties, Astellas. "This approval marks a significant milestone for patients living with this rare but serious bladder condition that can cause unwanted accidents."[3]

NDO is a type of bladder dysfunction caused by nerve damage and is marked by uncontrolled bladder contractions that can lead to symptoms of urinary frequency, urgency

[1] Hristov KL, Afeli SAY, Parajuli SP, Cheng Q, Rovner ES, *et al*. Neurogenic detrusor overactivity Is associated with decreased expression and function of the large conductance voltage- and Ca2+ -activated K+ channels. PLoS ONE 2013;8(7):1-8.

[2] McKibben MJ, Seed P, Ross SS, Borawski KM. Urinary Tract Infection and Neurogenic Bladder. Urol Clin North Am. 2015;42(4):527-536.

[3] Bauer SB, Austin PF, Rawashdeh YF, de Jong TP, Franco I, Siggard C, et al. International Children's Continence Society's recommendations for initial diagnostic evaluation and follow-up in congenital neuropathic bladder and bowel dysfunction in children. Neurourol Urodyn. 2012;31:610-4.

and incontinence.[1] Eighty-five percent of children with NDO have spina bifida, a congenital spinal cord defect.[3]

Myrbetriq tablets (mirabegron extended-release tablets) are currently available in the U.S. Myrbetriq Granules (mirabegron for extended-release oral suspension) were developed for ease of administration in younger children with NDO, or children with NDO who may have difficulty swallowing tablets, and will be available in the U.S. by the end of 2021.

“Astellas is a long-time leader in the field of urologic health and is committed to advancing the treatment of bladder conditions that adversely impact the lives of patients,” continued Mujais. “Since its initial approval nine years ago, Myrbetriq has been used to treat nearly 18 million adult patients worldwide with urological conditions.”[4]

The approval for the NDO indication was 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).

Astellas has already reflected the impact from this FDA approval in its financial forecast for the current fiscal year, ending March 31, 2021.

USE OF MYRBETRIQ (mirabegron extended-release tablets) and MYRBETRIQ GRANULES (mirabegron for extended-release oral suspension)

- Myrbetriq (mirabegron extended-release tablets) for oral use is a prescription medicine used to treat children 3 years of age and older weighing at least 77 pounds (35 kg), with a condition called neurogenic detrusor overactivity (NDO).
- Myrbetriq Granules (mirabegron for extended-release oral suspension) is a prescription medicine used to treat children 3 years of age and older with a condition called neurogenic detrusor overactivity (NDO).

It is not known if Myrbetriq tablets and Myrbetriq Granules to treat NDO are safe and effective in children under 3 years of age.

IMPORTANT SAFETY INFORMATION

Do not take Myrbetriq tablets or Myrbetriq Granules if you are allergic to mirabegron or any ingredients in Myrbetriq tablets or Myrbetriq Granules.

Myrbetriq tablets and Myrbetriq Granules may cause your blood pressure to increase or make your blood pressure worse if you have a history of high blood pressure. You and your doctor should check your blood pressure while you are taking Myrbetriq tablets or Myrbetriq Granules. Call your doctor if you have increased blood pressure.

Myrbetriq tablets and Myrbetriq Granules 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 tablets and Myrbetriq Granules may cause an allergic reaction with swelling of the face, lips, throat or tongue with or without difficulty breathing. Stop taking Myrbetriq tablets or Myrbetriq Granules and go to the nearest hospital emergency room right away.

Tell your doctor about all the medicines you take including medications for overactive bladder or other medicines especially thioridazine (Mellaril™ and Mellaril-S™), flecainide (Tambocor®), propafenone (Rythmol®), digoxin (Lanoxin®) or solifenacin succinate (VESIcare®). Myrbetriq tablets and Myrbetriq Granules may affect the way other medicines work, and other medicines may affect how Myrbetriq tablets and Myrbetriq Granules works.

[4]Astellas. Myrbetriq. Data on File.

Before taking Myrbetriq tablets and Myrbetriq Granules, tell your doctor about all of your medical conditions, including if you have liver or kidney problems.

The most common side effects of Myrbetriq tablets and Myrbetriq Granules in children with neurogenic detrusor overactivity include urinary tract infection, pain or swelling of the nose or throat (nasopharyngitis), constipation, and headache.

For further information, please talk to your healthcare professional and see accompanying Patient Product Information and complete Prescribing Information

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.

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.

###

Contacts for inquiries or additional information:

Astellas Portfolio Communications
Anna Otten
TEL: +1-847-682-4812
Anna.otten@astellas.com

Astellas Pharma Inc.
Corporate Advocacy & Relations
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473