Myrbetriq®, Myrbetriq® Granules (mirabegron extended-release) – New indication, new formulation approval

- On March 26, 2021, Astellas Pharma announced the FDA approval of Myrbetriq (mirabegron) tablets, for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older and weighing 35 kg or more.

- In addition to the new indication, the FDA also approved Myrbetriq Granules, a new oral suspension formulation. Myrbetriq Granules is approved for the treatment of NDO in pediatric patients aged 3 years and older.

- Myrbetriq tablets are also approved for the treatment of adult overactive bladder (OAB).

- NDO is a dysfunction of the bladder that results from congenital conditions (eg, spina bifida), or other disease or injury in the nervous system, such as spinal cord injury. If NDO is not treated, increased pressure in the bladder can put the upper urinary tract at risk of harm, including possible permanent damage to the kidneys. In addition, spontaneous bladder muscle contractions can lead to unexpected and frequent leakage of urine with symptoms of urinary urgency, frequency, and incontinence.

- The approval of Myrbetriq for the new indication was based on a 52-week, open-label, baseline-controlled, dose titration study in 86 pediatric patients 3 years of age and older with NDO. A total of 68 patients (43 patients 3 to less than 12 years of age and 25 patients 12 to 17 years of age) had valid urodynamic measurements for evaluation of efficacy. The primary endpoint was change from baseline in the patients' maximum cystometric (bladder) capacity (MCC) after 24 weeks of treatment.

    - The mean change from baseline in MCC in patients aged 3 to less than 12 years was 72 mL (95% CI: 45, 99).
    - The mean change from baseline in MCC in patients aged 12 years to 17 years was 113 mL (95% CI: 79, 147).

- In pediatric patients weighing less than 35 kg, the recommended starting dosage and maximum doses of Myrbetriq Granules are based on patient weight. In patients 11 kg to less than 22 kg, the starting dose is 3 mL (24 mg) orally once daily and the maximum volume is 6 mL (48 mg). For 22 kg to less than 35 kg, the starting dose is 4 mL (32 mg) once daily and the maximum volume is 8 mL (64 mg).

- In pediatric patients weighing 35 kg or more, the recommended starting dosage of Myrbetriq is 25 mg orally once daily. If needed, increase to a maximum dosage of Myrbetriq 50 mg once daily after 4 to 8 weeks. The recommended starting dosage of Myrbetriq Granules is 6 mL (48 mg) once daily. If needed, increase to a maximum dosage of Myrbetriq Granules 10 mL (80 mg) once daily after 4 to 8 weeks.

- Myrbetriq and Myrbetriq Granules are two different products and they are not substitutable on a milligram-per-milligram basis. The recommended product should be selected based on the indication and patient's weight.

- Refer to the Myrbetriq drug label for dosing in OAB.

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- Astellas Pharma plans to launch Myrbetriq Granules by the end of 2021. Myrbetriq Granules will be available as a 8 mg/mL oral suspension after reconstitution.

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