VESIcare LS™ (solifenacin succinate) – New drug approval

- On May 26, 2020, the FDA announced the approval of Astellas' VESIcare LS (solifenacin succinate) oral suspension, for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 2 years and older.

- NDO is a dysfunction of the bladder that results from disease or injury in the nervous system. NDO may be related to congenital conditions, such as spina bifida or other conditions such as spinal cord injury. With NDO, there is overactivity of the bladder wall muscle, which normally relaxes to allow storage of urine.

    — 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.

- VESIcare LS is the first FDA-approved treatment for NDO patients as young as two years of age.

- Solifenacin is also available generically as an oral tablet for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.

- The efficacy of VESIcare LS was established in two 52-week, open-label, baseline-controlled, sequential dose titration studies in a total of 95 pediatric patients 2 years of age and older with NDO. The primary efficacy endpoint was change from baseline in the patients' maximum cystometric (bladder) capacity (MCC) after 24 weeks of treatment.

    — As shown in the table below, an improvement in MCC was observed in patients aged 2 to less than 5 years of age and in patients aged 5 to 17 years of age.

	Aged 2 to less than 5 years (N = 17) Mean (SD)	**Aged 5 to 17 years (N = 49) Mean (SD)**
MCC (mL)		
Baseline	98 (40)	224 (133)
Week 24	137 (37)	279 (127)
Change from baseline	39 (36) 95% CI: 21, 57	57 (108) 95% CI: 26, 88

- VESIcare LS is contraindicated in patients:

    — With gastric retention
    — With uncontrolled narrow-angle glaucoma
    — Who have demonstrated hypersensitivity to solifenacin succinate or the inactive ingredients in VESIcare LS. Reported adverse reactions have included anaphylaxis and angioedema.

- Warnings and precautions for VESIcare LS include angioedema and anaphylactic reactions; urinary retention; gastrointestinal disorders; central nervous system effects; controlled narrow-angle glaucoma; and QT prolongation in patients at high risk of QT prolongation.

- The most common adverse reactions (> 2%) with VESIcare LS use were constipation, dry mouth and urinary tract infection.

Continued . . .

- The recommended starting and maximum VESIcare LS oral suspension doses are provided in the table below. VESIcare LS oral suspension has a concentration of 1 mg/1 mL. The recommended doses are weight-based and are administered once daily. After administration of the recommended starting dose, the dose may be increased to the lowest effective dose but should not exceed the maximum recommended dose.

    — Patients or their caregivers should be instructed that patients should take VESIcare LS orally followed by liquid (eg, water or milk).

Weight range	Starting dose	Maximum dose
9 kg to 15 kg	2 mL	4 mL
Greater than 15 kg to 30 kg	3 mL	5 mL
Greater than 30 kg to 45 kg	3 mL	6 mL
Greater than 45 kg to 60 kg	4 mL	8 mL
Greater than 60 kg	5 mL	10 mL

- Astellas plans to launch VESIcare LS in late 2020. VESIcare LS will be available as a 5 mg/5 mL (1 mg/1 mL) oral suspension.