Tezruly™ (terazosin) – New formulation approval

- On July 29, 2024, the FDA approved Novitium's Tezruly (terazosin) oral solution, for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH), and for the treatment of hypertension alone or with other antihypertensive agents, to lower blood pressure.

- Tezruly is the first oral solution formulation of terazosin.

- Warnings and precautions for Tezruly include syncope and ''first-dose'' effect; orthostatic hypotension; risk of hypotension with concomitant use of other antihypertensive agents and phosphodiesterase type 5 inhibitors; priapism; prostatic cancer; intraoperative floppy iris syndrome; and laboratory tests.

- The most common adverse reactions (≥ 1% of patients and at a higher incidence than placebo) with Tezruly use in BPH were asthenia, flu syndrome, postural hypotension, nausea, somnolence, vertigo, dyspnea, nasal congestion/rhinitis, blurred vision/amblyopia and erectile dysfunction.

- The most common adverse reactions (≥ 5%, where the incidence on terazosin was at least 2% and greater than placebo or where the reaction was of particular interest) with Tezruly use in hypertension were asthenia, back pain, pain in the extremities, headache, palpitations, postural hypotension, tachycardia, nausea, edema, peripheral edema, weight gain, depression, dizziness, decreased libido, nervousness, paresthesia, somnolence, dyspnea, nasal congestion, sinusitis, blurred vision, and erectile dysfunction.

- The recommended initial dose of Tezruly for BPH is 1 mg orally once daily at bedtime. This dose should not be exceeded as an initial dose. Patients should be closely followed during initial administration in order to minimize the risk of severe hypotensive response, including syncope.

    — The dose should be increased in a stepwise fashion from 2 mg to 10 mg orally once daily to achieve the desired improvement of symptoms and/or flow rates. Doses of 10 mg once daily are generally required for a clinical response. Therefore, treatment with 10 mg for a minimum of 4 weeks to 6 weeks may be required to assess whether a beneficial response has been achieved.

- The recommended initial dose of Tezruly for hypertension is 1 mg orally once daily at bedtime. The initial dosing regimen should not be exceeded to minimize the potential for severe hypotensive effects, including syncope.

    — The dose should be slowly increased to achieve the desired blood pressure response. The usual recommended dose range is 1 mg to 5 mg orally once daily; however, some patients may benefit from doses as high as 20 mg per day. Doses over 20 mg do not appear to provide further blood pressure effect and doses over 40 mg have not been studied.
    — Tezruly may be used alone or in combination with other antihypertensive agents. The dose of Tezruly and the dose frequency (every 12 hours or 24 hours) should be adjusted based on the patient's individual blood pressure response.

- Novitium's launch plans for Tezruly are pending. Tezruly will be available as a 1 mg/mL oral solution.