Zusduri™ (mitomycin) – New drug approval

- On June 12, 2025, the FDA announced the approval of UroGen's Zusduri (mitomycin), for the **treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)**.

- LG-IR-NMIBC affects around 82,000 people in the U.S. every year and of those, an estimated 59,000 are recurrent.

- Zusduri is an intravesical formulation of mitomycin, an alkylating drug.

- The efficacy of Zusduri was established in ENVISION, a single-arm study in 240 adults with recurrent LG-IR-NMIBC, of whom 223 were evaluable for response. The major outcome measures were complete response rate (CR) at 3 months (defined as no detectable disease in the bladder by cystoscopy, biopsy [if indicated], and urine cytology) and duration of response (DOR).

    - **The CR rate was 78%** (95% CI: 72, 83).
    - The DOR range was 0.0 to 25.0+ months and 79% had a DOR ≥ 12 months.

- Zusduri is contraindicated in patients with:

    - Perforation of the bladder
    - Prior hypersensitivity reactions to mitomycin or any component of the product.

- Warnings and precautions for Zusduri include risks in patients with perforated bladder and embryo-fetal toxicity.

- The most common adverse reactions (≥ 10%), including laboratory abnormalities, with Zusduri use were increased creatinine, increased potassium, dysuria, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, increased eosinophils, decreased lymphocytes, urinary tract infection, decreased neutrophils, and hematuria.

- The recommended dose of Zusduri is 75 mg (56 mL) instilled once weekly for six weeks into the bladder via a urinary catheter.

- UroGen plans to launch Zusduri on or around July 1, 2025. Zusduri will be available as a kit containing two 40 mg (each) single-dose vials of mitomycin for intravesical solution and one vial of 60 mL sterile hydrogel for reconstitution.