

Mitomycin Delivers Lasting Results in Hard-to-Treat Bladder Cancer, Phase 3 Data Show

Key Takeaways

- Recurrent LG-IR-NMIBC remains highly prevalent despite TURBT plus immediate intravesical chemotherapy, with substantial recurrence risk and a clinically meaningful minority progressing to metastatic disease.
- A catheter-delivered, sustained-release hydrogel formulation enables intravesical mitomycin chemoablation, supporting a non-surgical, induction-only strategy intended to reduce long-term recurrence burden.
- ENVISION enrolled 240 patients; 80% achieved 3-month CR, and responders had 72% Kaplan–Meier event-free probability at 24 months, with 36 low-grade recurrences.
- Safety was dominated by dysuria, hematuria, UTI, and laboratory shifts; serious adverse reactions occurred in 12%, including urinary retention (0.8%) and urethral stenosis (0.4%).
- Regulatory clearance in June 2025 established an FDA-approved option specifically for adults with recurrent LG-IR-NMIBC, positioning this approach as a potential practice-changing standard.

ENVISION trial shows mitomycin intravesical solution after TURBT delivers durable control in recurrent NMIBC, with 72% event-free at 24 months.

Mitomycin intravesical solution (Zusduri; UroGen Pharma Ltd) demonstrated a 72.2% probability of remaining event-free in patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). The long-term data from the phase 3 ENVISION trial (NCT05243550) further establish the clinical benefit of mitomycin and support the agent’s FDA approval in June of 2025.¹

“The publication of these long-term data in *The Journal of Urology* provides important peer-reviewed validation of the durability of [mitomycin] treatment observed in the ENVISION trial,” said Sandip Prasad, MD, MPhil, director of Genitourinary Surgical Oncology and vice chair of Urology at Morristown Medical Center/Atlantic Health System, New Jersey, and principal investigator of the ENVISION trial. “For patients who achieved a complete response, the likelihood of remaining event-free through 2 years was substantial, underscoring the potential of [mitomycin] to change the long-term management of this highly recurrent disease with a 6-week induction treatment alone without maintenance. For the first time, adult patients with recurrent LG-IR-NMIBC have an FDA-approved therapy.”²

The NMIBC Treatment Landscape

Bladder cancer is the most common urologic cancer and is expected to affect over 84,000 patients in 2026. In newly diagnosed patients, approximately 75% will present with non-muscle invasive bladder cancer (NMIBC). Although 5-year survival rates reach an approximate 73%, over 50% of patients experience recurrence, and 30% will progress to metastatic disease.³

The standard of care for NMIBC is transurethral resection of bladder tumor (TURBT). TURBT is a surgical procedure used for the diagnosis and treatment of bladder cancers. This is followed by a single dose of intravesical chemotherapy, such as mitomycin, within 24 hours of surgery.

Clinical trial and real-world data show that this combination can reduce the 5-year recurrence rate by approximately 35%.³

Mitomycin and the ENVISION Trial

Mitomycin intravesical solution is a sustained release, hydrogel-based formula that is delivered directly into the bladder using a urinary catheter. The innovative drug formulation of mitomycin received FDA approval in 2025 for the treatment of adults with recurrent LG-IR-NMIBC. This decision was supported by data from the phase 3, single-arm, multicenter ENVISION trial evaluating the safety and efficacy of mitomycin as a chemoablative therapy in patients with LG-IR-NMIBC at intermediate risk (IR) of recurrence.²

Enrolled patients (n = 240; 98% White; 61% male; 68% aged \geq 65 years) received 1 or more doses of mitomycin intravesical solution. At 3 months, 191 patients (80%; 95% CI: 74-85) achieved a complete response (CR) with a probability of remaining event-free 24 months after CR was 72% (95% CI: 64-79; Kaplan–Meier estimate). Among patients with CR at 3 months, 36 developed low-grade disease recurrence.⁴

The most common adverse effects (AEs) reported were dysuria, hematuria, urinary tract infection, increased creatinine, increased potassium, decreased hemoglobin, decreased lymphocytes, decreased neutrophils, increased eosinophils, and increased liver enzymes (AST and ALT). AEs were primarily mild to moderate in severity. Serious adverse reactions occurred in 12% of patients and included urinary retention (0.8%) and urethral stenosis (0.4%).²

Mitomycin and a Potential New Standard of Care

With peer-reviewed long-term data now published and FDA approval secured, mitomycin intravesical solution marks a notable shift in how recurrent LG-IR-NMIBC may be managed going forward. The ENVISION trial results provide the clinical foundation needed to support its adoption, and ongoing real-world use will help clarify its full impact on patient outcomes.

REFERENCES

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