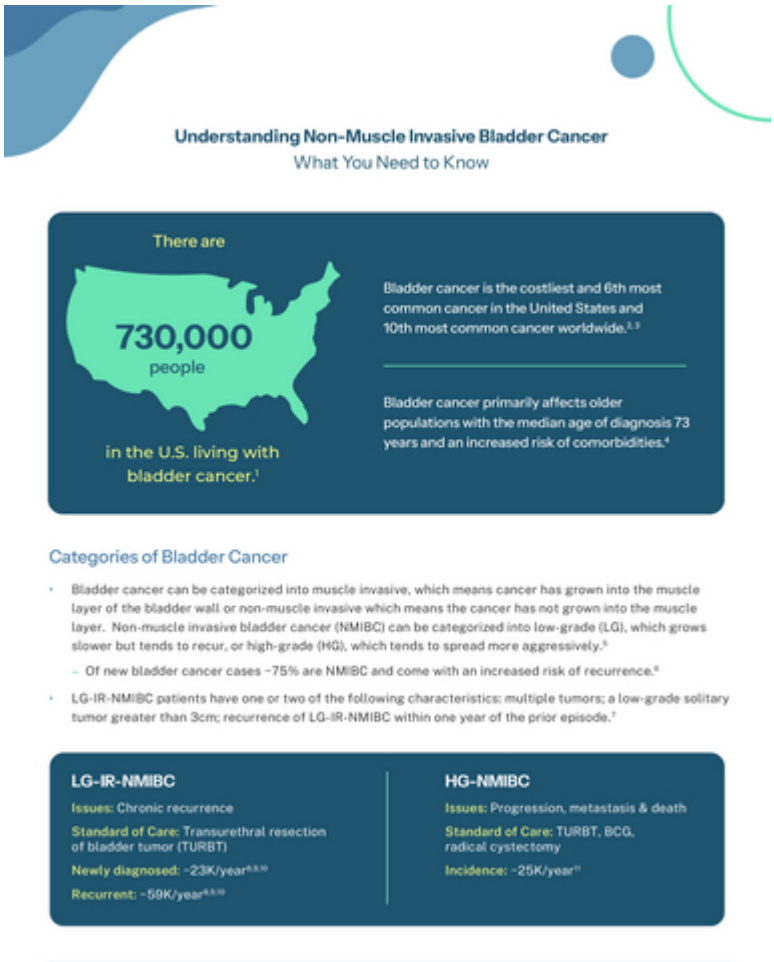
# U.S. FDA Approves UroGen's ZUSDURI™ (mitomycin) for Intravesical Solution as the First and Only Medication for Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)

June 12, 2025

- *ZUSDURI (formerly known as UGN-102) is a localized medication designed for potent tumor ablation delivered by innovative RTGel® technology.*
- *Approval supported by pivotal Phase 3 ENVISION trial demonstrating 78% of patients achieved complete response (CR) at 3 months, and 79% of those responders maintained complete response at 12 months after the 3-month visit (DOR).*
- *Manageable safety profile characterized primarily by mild to moderate lower urinary tract symptoms.*
- *An estimated 59,000 LG-IR-NMIBC patients in the U.S. recur each year and face repeat surgeries.*
- *Conference call and webcast to be held on June 13, 2025, at 8:30 AM ET*




PRINCETON, N.J.--(BUSINESS WIRE)--Jun. 12, 2025-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced the U.S. Food and Drug Administration (FDA) approved ZUSDURI, the first and only FDA-approved medication for adults with recurrent LG-IR-NMIBC. ZUSDURI consists of mitomycin and sterile hydrogel, using UroGen's proprietary sustained release *RTGel®* technology. ZUSDURI has been designed for potent tumor ablation. This landmark approval is based on the positive results from the Phase 3 ENVISION trial that demonstrated ZUSDURI delivers 78% complete response (CR) for patients at 3 months, and of those patients 79% remained event-free 12 months later.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20250610841284/en/

"The approval of ZUSDURI represents a significant step forward for our company and for the treatment of recurrent LG-IR-NMIBC," said Liz Barrett, President and CEO of UroGen. "For the first time, the estimated 59,000 U.S. patients facing recurrent LG-IR-NMIBC each year have access to an FDA-approved medicine. This historic achievement is a bold leap forward in our mission to redefine uro-oncology and bring innovation to patients who

need it most. We are deeply grateful to the FDA for their collaboration and to the investigators, patients, and caregivers whose commitment made this milestone possible. Their contributions have been essential in bringing meaningful innovation to the bladder cancer community."

The existing standard of care for LG-IR-NMIBC is a surgical procedure typically performed under general anesthesia called transurethral resection of bladder tumor (TURBT). Due to high recurrence rates of LG-IR-NMIBC, repeat TURBTs may be necessary.

"ZUSDURI marks a breakthrough in uro-oncology, offering a new alternative for recurrent LG-IR-NMIBC patients who can live for many years with the disease but often endure multiple resections, under general anesthesia," said Dr. Sandip Prasad, MD, M.Phil., Director of Genitourinary Surgical Oncology at Morristown Medical Center/Atlantic Health System, NJ, and principal investigator of the ENVISION trial. "For decades, TURBT has been the standard approach for bladder cancer treatment. That's why innovative treatments like ZUSDURI are essential, especially for those adult patients with recurrent low-grade, intermediate-risk NMIBC."

The most common (≥ 10%) adverse reactions, including laboratory abnormalities, that occurred in patients 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. Serious adverse reactions occurred in 12% of patients who received ZUSDURI, including, urinary retention (0.8%) and urethral stenosis (0.4%).

**Product Availability**

ZUSDURI is expected to be available in the U.S. on or around July 1, 2025, for the treatment of adults with recurrent LG-IR-NMIBC. In the interim, patients can visit ZUSDURI.com (available soon).

**UroGen Patient Support**

UroGen is committed to helping patients access ZUSDURI. UroGen Support may help identify appropriate financial assistance programs for eligible patients with commercial, Medicare or Medicaid coverage, as well as those with no insurance coverage. These programs are for eligible patients who have been prescribed ZUSDURI and who need help managing the cost of treatment. The appropriate program will depend on the patient's insurance coverage. Visit ZUSDURI.com (available soon) or contact UroGen Support at 1-833-UROGEN-1 (1-833-876-4361) for additional information.

**Post-Marketing Commitment**

As a post-marketing commitment, UroGen has agreed with the FDA to complete the ongoing ENVISION trial to further characterize the clinical benefit of ZUSDURI for the treatment of patients with recurrent LG-IR-NMIBC. In addition, UroGen committed to provide the FDA annual updates on duration of response (DOR) for all patients with ongoing complete responses. The annual updates will continue until all ongoing patients experience a recurrence of LG-IR-NMIBC; progression; death; loss to follow-up; or reach 63 months after the first instillation as planned in the protocol, whichever occurs first.

**Conference Call & Webcast Information**

Members of UroGen's management team will host a live conference call and webcast on June 13, 2025 at 8:30 AM Eastern Time to review ZUSDURI approval details and commercialization plans. The live webcast can be accessed by visiting the Investors section of the Company's website at http://investors.urogen.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. An archive of the webcast will be available on the Company's website.

**About ZUSDURI**

ZUSDURI (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin, approved for the treatment of adults with recurrent LG-IR-NMIBC. Utilizing UroGen's proprietary *RTGel*® technology, a sustained release, hydrogel-based formulation, ZUSDURI is delivered directly into the bladder in an out-patient procedure by a trained healthcare professional using a urinary catheter to enable the treatment of tumors by non-surgical means.

**About Non-Muscle Invasive Bladder Cancer (NMIBC)**

LG-IR-NMIBC affects around 82,000 people in the U.S. every year and of those, an estimated 59,000 are recurrent. Bladder cancer primarily affects older populations with increased risk of comorbidities, with the median age of diagnosis being 73 years. Guideline recommendations for the management of NMIBC include TURBT as the standard of care. Up to 70 percent of NMIBC patients experience at least one recurrence, and LG-IR-NMIBC patients are even more likely to recur and face repeated TURBT procedures. Learn more about non-muscle invasive bladder cancer at www.BladderCancerAnswers.com.

**About UroGen Pharma Ltd.**

UroGen is a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers because patients deserve better options. UroGen has developed RTGel reverse-thermal hydrogel, a proprietary sustained-release, hydrogel-based platform technology that has the potential to improve the therapeutic profiles of existing drugs. UroGen's sustained release technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. Our first product to treat low-grade upper tract urothelial cancer and ZUSDURI (mitomycin) for intravesical solution, UroGen's first product to treat recurrent LG-IR-NMIBC are both designed to ablate tumors by non-surgical means. UroGen is headquartered in Princeton, NJ with operations in Israel. Visit www.UroGen.com to learn more or follow us on X, @UroGenPharma.

**APPROVED USE FOR ZUSDURI**

ZUSDURI (mitomycin) for intravesical solution is a prescription medicine used to treat adults with a type of cancer of the lining of the bladder called low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC) after previously receiving bladder surgery to remove tumor that did not work or is no longer working.

**IMPORTANT SAFETY INFORMATION**

**You should not receive ZUSDURI if you** have a hole or tear (perforation) of your bladder or if you have had an allergic reaction to mitomycin or to any of the ingredients in ZUSDURI.

**Before receiving ZUSDURI, tell your healthcare provider about all of your medical conditions, including if you:**

- have kidney problems

- are pregnant or plan to become pregnant. ZUSDURI can harm your unborn baby. You should not become pregnant during treatment with ZUSDURI. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ZUSDURI.

  **Females who are able to become pregnant:** You should use effective birth control (contraception) during treatment with ZUSDURI and for 6 months after the last dose.

  **Males being treated with ZUSDURI:** You should use effective birth control (contraception) during treatment with ZUSDURI and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if ZUSDURI passes into your breast milk. Do not breastfeed during treatment with ZUSDURI and for 1 week after the last dose.

**How will I receive ZUSDURI?**

- You will receive your ZUSDURI dose from your healthcare provider 1 time a week for 6 weeks into your bladder through a tube called a urinary catheter. It is important that you receive all 6 doses of ZUSDURI according to your healthcare provider's instructions.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.
- During treatment with ZUSDURI, your healthcare provider may tell you to take additional medicines or change how you take your current medicines.

**After receiving ZUSDURI:**

- ZUSDURI may cause your urine color to change to a violet to blue color. Avoid contact between your skin and urine for at least 24 hours.
- To urinate, **males and females should sit** on a toilet and flush the toilet several times after you use it. After going to the bathroom, wash your hands, your inner thighs, and genital area well with soap and water.
- Clothing that comes in contact with urine should be washed right away and washed separately from other clothing.

**The most common side effects of ZUSDURI include:** increased blood creatinine levels, increased blood potassium levels, trouble with urination, decreased red blood cell counts, increase in certain blood liver tests, increased or decreased white blood cell counts, urinary tract infection, and blood in your urine.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to UroGen Pharma at 1-855-987-6436.

**Please see ZUSDURI Full Prescribing Information, including the Patient Information, for additional information.**



**Forward-Looking Statements**

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, statements regarding: the estimated annual U.S. patient population and demographics for LG-IR-NMIBC; the potential benefits to patients and opportunities for ZUSDURI; the potential of UroGen's proprietary *RTGel* technology to improve therapeutic profiles of existing drugs other than mitomycin; and UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. Words such as "can," "expect," "may," "plan," "potential," "target," "will" or other words that convey uncertainty of future events or outcomes are used to identify these forward-looking statements. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the ability to maintain regulatory approval; complications associated with commercialization activities; labeling limitations; competition in UroGen's industry; the scope, progress and expansion of developing and commercializing UroGen's products and product candidates; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies or procedures, such as surgery; UroGen's ability to attract or retain key management, members of the board of directors and other personnel; UroGen's *RTGel* technology and ZUSDURI may not perform as expected; new data relating to ZUSDURI, including from spontaneous adverse event reports and from the ongoing ENVISION trial, may result in changes to the product label and may adversely affect sales, or result in withdrawal of ZUSDURI from the market; the potential for payors to delay, limit or deny coverage for ZUSDURI; and UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGel* technology. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC on May 12, 2025. The events and circumstances discussed in such forward-looking statements may not occur, and UroGen's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to UroGen as of the date of this release.

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