Journal of Urology Publishes ENVISION Trial Results Showing 72.2% 24-Month Duration of Response with ZUSDURI

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- 72.2% Probability of Remaining Event-Free at 24 Months by Kaplan-Meier Analysis After Achieving Complete Response at Three Months (79.6%)

PRINCETON, N.J., March 30, 2026 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced the publication of results from the pivotal Phase 3 ENVISION trial of ZUSDURI™ (mitomycin) for intravesical solution in*The Journal of Urology*. ZUSDURI is indicated for the treatment of adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC). The publication reports a 72.2% probability of remaining event-free at 24 months after complete response (CR) (95% CI: 64%, 79%) as determined by Kaplan-Meier analysis. The CR rate at three months was 79.6%. The median follow-up time after three-month CR was 23.7 months, and the median DOR was not reached.

“The publication of these long-term data in *The Journal of Urology* provides important peer-reviewed validation of the durability of ZUSDURI treatment observed in the ENVISION trial,” said Sandip Prasad, M.D., M.Phil., 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 two years was substantial, underscoring the potential of ZUSDURI to change the long-term management of this highly recurrent disease with a six-week induction treatment alone without maintenance. For the first time, adult patients with recurrent LG-IR-NMIBC have an FDA-approved therapy.”

The existing standard of care for LG-IR-NMIBC is transurethral resection of bladder tumor (TURBT), a surgical procedure typically performed under general anesthesia. Due to high recurrence rates, patients, who are often elderly with multiple comorbidities, may require repeated TURBT procedures over their lifetime, which can negatively impact quality of life and may be associated with increased health risks. An estimated 59,000 patients with LG-IR-NMIBC experience recurrence annually in the United States.

“Now that the 24-month duration of response data from ENVISION are published in a leading urology journal, we’re seeing even stronger validation of ZUSDURI’s clinical impact,” said Mark Schoenberg, Chief Medical Officer, UroGen. “As the first and only approved treatment for recurrent LG-IR-NMIBC, ZUSDURI gives patients a real chance at meaningful, recurrence-free periods. These results suggest we may finally be able to break the long-standing cycle of repeated recurrences and surgeries that has defined care for patients with recurrent LG-IR-NMIBC.”

The most common (≥10%) adverse reactions, including laboratory abnormalities, observed in patients treated with ZUSDURI 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). Adverse reactions 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%).

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 by a trained healthcare professional using a urinary catheter in an outpatient setting, thereby enabling 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 transurethral resection of bladder tumor (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 is approved to treat low-grade upper tract urothelial cancer, and our second product, ZUSDURI (mitomycin) for intravesical solution, is approved for adult patients with recurrent LG-IR-NMIBC. Both products are 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 potential long-term benefits of ZUSDURI, including its potential to provide meaningful recurrence-free periods; the estimated annual U.S. patient population and demographics for LG-IR-NMIBC; 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," "estimate," "likely," "may," "potential," "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: clinical results may not be indicative of results that may be observed in the future, including in larger populations; potential safety and other complications related to UroGen's products; the ability to maintain regulatory approval; labeling limitations; competition in UroGen's industry; 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; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGel* technology; and the impacts of general macroeconomic and geopolitical conditions on UroGen's business and financial position. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 2, 2026, 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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