ZUSDURI Median Duration of Response Still Not Reached with 64.5% 36-month Duration of Response in the Pivotal ENVISION Trial

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- 64.5% Probability of Remaining Event-Free at Three Years by Kaplan-Meier Analysis After Achieving Complete Response at Three Months
- First and Only FDA-Approved Medicine for Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer

PRINCETON, N.J., May 13, 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 a 36-month duration of response (DOR) of 64.5% (95% CI, 54.6% - 72.8%) by Kaplan-Meier estimate in patients who achieved a complete response (CR) at three months (79.6%) in the pivotal Phase 3 ENVISION trial of ZUSDURI™ (mitomycin) for intravesical solution. At a median follow-up of 35.5 months, the median DOR had not been reached. These data demonstrate that a substantial proportion of complete responders remained disease-free at three years, and durable outcomes were achieved without the need for maintenance therapy.

“This update from the pivotal ENVISION trial shows that many patients who achieve a complete response with ZUSDURI remain disease-free through three years,” said Sandip Prasad, M.D., M.Phil., Director of Genitourinary Surgical Oncology and Vice Chair of Urology at Morristown Medical Center/Atlantic Health System, NJ, and Principal Investigator of the ENVISION trial. “Among patients who achieved a complete response, the event rate over time has remained stable. Importantly, ZUSDURI’s durability was achieved without maintenance therapy, supporting a treatment approach that can provide lasting disease control while reducing ongoing treatment burden for patients.”

As a non-surgical, in-office treatment, ZUSDURI offers patients an opportunity to achieve meaningful disease- and treatment-free living without the burden of repeated TURBT procedures under general anesthesia. The current 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 following surgery, patients often undergo multiple TURBTs over their lifetime, leading to a cycle of repeat procedures that can impact quality of life and increase cumulative risk, particularly in older patients with comorbidities. An estimated 59,000 patients with LG-IR-NMIBC recur annually.

“The ENVISION 36-month DOR data reinforce ZUSDURI’s potential to shift the treatment paradigm for recurrent LG-IR-NMIBC,” said Mark Schoenberg, M.D., Chief Medical Officer, UroGen. “By delivering durable responses without maintenance therapy, ZUSDURI provides an opportunity to move beyond the cycle of repeated surgical interventions and toward a more durable, lower-burden treatment approach over time.”

The most common (≥ 10%) adverse reactions (ARs), including laboratory abnormalities, that occurred in patients were dysuria, increased potassium, increased creatinine, decreased hemoglobin, increased eosinophils, increased aspartate aminotransferase, increased alanine aminotransferase, decreased lymphocytes, urinary tract infection, decreased neutrophils, and hematuria. ARs were mainly mild to moderate. Serious ARs occurred in 12% of patients, including 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 United States 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 ENVISION
The Phase 3 ENVISION trial is a single-arm, multinational, multicenter pivotal study evaluating the efficacy and safety of ZUSDURI (mitomycin) for intravesical solution as a chemoablative therapy in adult patients with recurrent LG-IR-NMIBC. The Phase 3 ENVISION trial completed target enrollment with 240 patients across 56 sites. Study participants received six once-weekly intravesical instillations of ZUSDURI. The primary endpoint evaluated the CR rate three months after the first instillation, and the key secondary endpoint evaluates durability over time in patients who achieved a CR at the three-month assessment. Learn more about the Phase 3 ENVISION trial at www.clinicaltrials.gov (NCT05243550).

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 our second product, ZUSDURI (mitomycin) for intravesical solution for adult patients with recurrent LG-IR-NMIBC, 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 (Twitter), @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 benefits of ZUSDURI, including as an outpatient treatment option, its potential to provide durable CRs without maintenance therapy and clinically meaningful disease- and recurrence-free intervals; the potential of ZUSDURI to shift the treatment paradigm and provide a compelling non-surgical alternative to TURBT for the treatment of recurrent LG-IR-NMIBC; the estimated annual U.S. patient population and demographics for LG-IR-NMIBC; the ongoing Phase 3 ENVISION trial; 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; 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; 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 Quarterly Report on Form 10-Q being filed with the SEC on May 6, 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.

INVESTOR CONTACT:
Vincent Perrone
Senior Director, Investor Relations
vincent.perrone@UroGen.com

609-460-3588 ext. 1093

MEDIA CONTACT:
Cindy Romano
Director, Corporate Communications
Cindy.romano@urogen.com
609-460-3566 ext. 1083

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