



UroGen Receives New U.S. Patent Allowance Expected to Provide Protection into July 2044 for ZUSDURI™ and UGN-103

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PRINCETON, N.J., July 15, 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 that it has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for patent application no. 18/784,354 entitled "Treatment of Low-Grade Intermediate-Risk Non-Muscle-Invasive Bladder Cancer With a Thermally Gelling Pharmaceutical Composition Containing Mitomycin." The allowed claims cover methods of treating patients with recurrent, low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) without a transurethral resection of a bladder tumor (TURBT), supported by data from the ENVISION and ATLAS clinical trials. The U.S. patent, once issued, will have an expiration date in July 2044.

"This patent allowance further strengthens the intellectual property foundation supporting ZUSDURI and our UGN-103 investigational medicine, if approved, and underscores the innovation behind our proprietary *RTGel*® technology," said Liz Barrett, President and Chief Executive Officer of UroGen. "Supported by data from the ENVISION and ATLAS trials of ZUSDURI, these patent claims reflect the ability of our *RTGel*-based technology to deliver mitomycin as a primary, non-surgical treatment option for adults with recurrent LG-IR-NMIBC without a TURBT. We believe this approach helps patients achieve highly durable recurrence-free intervals while reducing the burden of repeat surgical interventions."

Building on the growing body of clinical evidence supporting ZUSDURI and UGN-103, UroGen remains focused on advancing its proprietary *RTGel* technology and developing innovative therapies that have the potential to expand non-surgical treatment options for patients with urothelial cancers and strengthen the company's long-term growth opportunities.

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 UGN-103

In January 2024, UroGen entered into a licensing and supply agreement with medac to develop UGN-103 for recurrent LG-IR-NMIBC. UGN-103 is designed to reinforce and extend the clinical and commercial profile of ZUSDURI, the first and only FDA-approved treatment for adults with recurrent LG-IR-NMIBC. The program maintains UroGen's innovative and proven *RTGel* technology, enabling sustained mitomycin exposure in the bladder, while incorporating next-generation enhancements, including a more streamlined manufacturing process and simplified reconstitution to support improved ease of use in clinical practice. UroGen holds U.S. patents covering the combination of its proprietary *RTGel* technology with medac's licensed lyophilized mitomycin formulation, as well as the use of UGN-103 in LG-IR-NMIBC, with intellectual property protection expected to extend into December 2041.

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 (formerly Twitter), @UroGenPharma.

About medac

At medac group, we believe that health is humanity's most valuable resource. Since 1970, our mission has been to improve patients' quality of life worldwide by making the best medical treatments available. As a globally operating pharmaceutical company headquartered in Germany, we provide high-quality medical treatments for patients worldwide in over 90 countries. With more than 2,000 employees, we are committed to improving human health.

Our products are manufactured in Germany and other European countries to the highest standards, utilizing our own logistics center and production sites, and subsequently distributed worldwide.

We are constantly working to improve authorized medicines and to develop innovative therapies in the fields of rheumatology, urology, hematology, and oncology. Part of our mission is to provide safe, high-quality and innovative original products, as well as generics and biosimilars. In this way, we make vital treatments accessible to those affected.

For more information, please visit www.medac-group.com.

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 approval of UroGen's U.S. patent application covering methods of treating patients with recurrent LG-IR-NMIBC without a TURBT, and the expected expiration date of such patent in July 2044; the expected benefits of the new U.S. patent allowance, including strengthening UroGen's intellectual property foundation and demonstrating the innovation behind UroGen's proprietary *RTGeI* technology; the potential of UGN-103, if approved, to advance care for adult patients with recurrent LG-IR-NMIBC, build on UroGen's leadership in uro-oncology, expand its commercial portfolio, drive long-term growth supported by streamlined manufacturing and reconstitution processes and extend intellectual property protection into December 2044; the potential benefits of ZUSDURI and UGN-103, if approved, including its potential to achieve highly durable recurrence-free intervals while reducing the burden of repeat surgical interventions; the potential of UroGen's proprietary *RTGeI* technology to improve therapeutic profiles of existing drugs other than mitomycin and expand non-surgical treatment options for patients with urothelial cancers; and UroGen's sustained release technology making local delivery a potentially more effective treatment option. Words such as "believe," "can," "estimated," "expect," "may," "plan," "potential," 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: preliminary clinical results may not be indicative of results that may be observed in the future; potential safety and other complications related to UroGen's products and product candidates; risks related to our and our licensors' ability to protect our respective patents and other intellectual property, including the fact that UroGen's or our licensors' pending patent applications may not be successful, and in such event, the duration of intellectual property protection would be more limited; 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 *RTGeI* technology and UroGen's products and product candidates may not perform as expected; the data from the UTOPIA trial may not be sufficient to support approval of UGN-103; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGeI* 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 for the quarter ended March 31, 2026, 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.

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