UroGen Announces Agreement Resolving Patent Litigation Relating to JELMYTO® (mitomycin) for pyelocalyceal solution

June 2, 2026

- *Agreement reinforces the value of UroGen's innovation and reflects the strength of the Company's intellectual property portfolio*
- *Teva will be granted a non-exclusive license to sell its generic version of JELMYTO beginning on September 15, 2030, if approved by the FDA*

PRINCETON, N.J., June 02, 2026 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq: URGN), a biotechnology company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that it has entered into a settlement and license agreement (the "Agreement"') with Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals, USA, Inc. (collectively, "Teva"). This Agreement resolves the patent litigation UroGen initiated in response to Teva's submission of an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of JELMYTO® (mitomycin) for pyelocalyceal solution prior to the expiration of the relevant Company patents. Please note, that the Teva ANDA has not received tentative approval from the FDA, according to the Agency's public database.

Under the terms of the Agreement, UroGen will grant Teva a non-exclusive license to sell its generic version of JELMYTO beginning on September 15, 2030, if approved by the FDA, unless certain limited circumstances customarily included in these types of agreements occur. In accordance with the Agreement, the parties will ask the court to dismiss the pending patent litigation with prejudice.

"We believe this resolution underscores the innovation behind our RTGel® technology and the strength of our intellectual property portfolio," said Liz Barrett, President and Chief Executive Officer of UroGen. "We look forward to continuing to execute on our mission to transform paradigms in uro-oncology with our innovative treatments."

JELMYTO has regulatory exclusivity through April 15, 2027, and is covered by Orange Book-listed patents expiring on January 20, 2031. The negotiated license date preserves nearly all of this patent protection period, reflecting the strength of the Company's intellectual property.

As required by law, the companies will submit the Agreement to the U.S. Federal Trade Commission and U.S. Department of Justice for review.

About JELMYTO

JELMYTO® (mitomycin) for pyelocalyceal solution is a mitomycin-containing reverse thermal gel containing 4 mg mitomycin per mL gel approved for the treatment of adult patients with LG-UTUC. JELMYTO is a viscous liquid when cooled and becomes a semi-solid gel at body temperature. The drug slowly dissolves over four to six hours after instillation and is removed from the urinary tract by normal urine flow and voiding. It is approved for administration in a retrograde manner via ureteral catheter or antegrade through a nephrostomy tube. The delivery system allows the initial liquid to coat and conform to the upper urinary tract anatomy. The eventual semisolid gel allows for chemoablative therapy to remain in the collecting system for four to six hours without immediately being diluted or washed away by urine flow.

About Upper Tract Urothelial Cancer

Urothelial cancer is the ninth most common cancer globally and the eighth most lethal neoplasm in men in the U.S. Between five percent and ten percent of primary urothelial cancers originate in the ureter or renal pelvis and are collectively referred to as UTUC. In the U.S., there are approximately 6,000 - 7,000 new or recurrent LG-UTUC patients annually. Most cases are diagnosed in patients over 70 years old, and these older patients often have multiple comorbidities. There are limited treatment options for UTUC, with the most common being endoscopic surgery or nephroureterectomy (removal of the entire kidney and ureter). Treatment with endoscopic surgery can be associated with a high rate of recurrence and relapse.

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 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 JELMYTO

JELMYTO® is a prescription medicine used to treat adults with a type of cancer of the lining of the upper urinary tract including the kidney called low-grade Upper Tract Urothelial Cancer (LG-UTUC).

IMPORTANT SAFETY INFORMATION

You should not receive JELMYTO if you have a hole or tear (perforation) of your bladder or upper urinary tract.

Before receiving JELMYTO, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. JELMYTO can harm your unborn baby. You should not become pregnant during treatment with JELMYTO. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with JELMYTO. **Females who are able to become pregnant:** You should use effective birth control (contraception) during treatment with JELMYTO and for 6 months after the last dose. **Males being treated with JELMYTO:** If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with JELMYTO and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if JELMYTO passes into your breast milk. Do not breastfeed during treatment with JELMYTO and for 1 week after the last dose.
- **Tell your healthcare provider if you take water pills (diuretic).**

How will I receive JELMYTO?

- Your healthcare provider will tell you to take a medicine called sodium bicarbonate before each JELMYTO treatment.
- You will receive your JELMYTO dose from your healthcare provider 1 time a week for 6 weeks. It is important that you receive all 6 doses of JELMYTO according to your healthcare provider's instructions. If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment. Your healthcare provider may recommend up to an additional 11 monthly doses.
- JELMYTO is given to your kidney through a tube called a catheter.
- During treatment with JELMYTO, your healthcare provider may tell you to take additional medicines or change how you take your current medicines.

After receiving JELMYTO:

- JELMYTO may cause your urine color to change to a violet to blue color. Avoid contact between your skin and urine for at least 6 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.

JELMYTO may cause serious side effects, including:

- **Swelling and narrowing of the tube that carries urine from the kidney to the bladder (ureteric obstruction).** If you develop swelling and narrowing, and to protect your kidney from damage, your healthcare provider may recommend the placement of a small plastic tube (stent) in the ureter to help the kidney drain. Tell your healthcare provider right away if you develop side pain or fever during treatment with JELMYTO.
- **Bone marrow problems.** JELMYTO can affect your bone marrow and can cause a decrease in your white blood cell, red blood cell, and platelet counts. Your healthcare provider will do blood tests prior to each treatment to check your blood cell counts during treatment with JELMYTO. Your healthcare provider may need to temporarily or permanently stop JELMYTO if you develop bone marrow problems during treatment with JELMYTO.
- **The most common side effects of JELMYTO include:** urinary tract infection, blood in your urine, side pain, nausea, trouble with urination, kidney problems, vomiting, tiredness, stomach (abdomen) pain.

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 JELMYTO Full Prescribing Information, including the Patient Information, for additional information.

Forward-Looking Statements

This statement contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without

limitation, statements regarding: the anticipated dismissal of the pending patent litigation with prejudice; UroGen's ability to transform paradigms with its solutions; the strength of UroGen's intellectual property portfolio and the value of UroGen's innovation; the potential for UroGen to transform urothelial cancer treatments; the strength of UroGen's patents and UroGen's plans to vigorously defend its intellectual property rights; the patient population for UTUC; the potential of UroGen's proprietary *RTGel* technology to improve therapeutic profiles of existing drugs; and UroGen's sustained release technology making local delivery potentially more effective as compared to other treatment options. Words and phrases such as "believe," "can" "expected," "if," "look forward to," "may," "plans to" "potential," "will," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: uncertainties related to whether UroGen's patent-infringement lawsuit against Teva will be successful; the ability obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; the costs and outcome of legal proceedings to enforce such intellectual property rights, including the lawsuit against Teva; competition in UroGen's industry, including the potential approval and introduction of generic or branded products that compete with UroGen's product or product candidates; and the ability to maintain regulatory approval; complications associated with commercialization activities; the scope, progress and expansion of developing and commercializing UroGen's product candidates; the timing and success of clinical trials and potential safety and other complications thereof; the size and growth of the market(s) for UroGen's product and product candidates and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; UroGen's *RTGel* technology may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGel* technology; UroGen's ability to attract or retain key management, members of the board of directors and personnel; and UroGen's financial condition and need for

additional capital in the future.. 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-Q for the first 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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