UroGen Receives New U.S. Patent Allowance for Next-Generation Mitomycin-Based Products Expected to Provide Protection Until December 2041

September 16, 2024

- **Once issued, this patent provides U.S. intellectual property coverage of UroGen's *RTGel*® technology with medac lyophilized mitomycin formulation, covering UGN-103 and UGN-104 development programs until December 2041**

PRINCETON, N.J.--(BUSINESS WIRE)--Sep. 16, 2024-- 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 United States Patent and Trademark Office (USPTO) for patent application no. 18/535,108 entitled "*Material and Method for Treating Cancer*."

The allowed claims relate to the combination of UroGen's *RTGel*® technology with medac's licensed proprietary lyophilized mitomycin formulation and cover the use of UroGen's UGN-103 and UGN-104 development programs in the treatment of low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) and low-grade upper tract urothelial cancer (LG-UTUC), respectively. The U.S. patent, once issued, will have an expiration date in December 2041.

"Allowance of this patent application strengthens our intellectual property position for our next-generation investigational programs for patients with urothelial cancers," said Liz Barrett, President and CEO of UroGen. "We believe that the combination of UroGen's *RTGel*® technology with medac's patent-protected lyophilized mitomycin has the potential to provide advantages related to production, cost, supply, and product convenience for patients. Our vision remains to develop innovative medicines that advance the care of patients, and this patent allowance is a key element of our strategy to build a long-term growth company."

In January 2024, UroGen entered into a licensing and supply agreement with medac to develop UGN-103 for LG-IR-NMIBC and UGN-104 for LG-UTUC. In April 2024, the FDA accepted UroGen's IND application for UGN-103 and the company is currently onboarding clinical sites for the study. The company anticipates commencing a similar study for UGN-104, which is expected in early 2025.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin, currently in Phase 3 development for the treatment of LG-IR-NMIBC. Utilizing UroGen's proprietary *RTGel*® technology, a sustained release, hydrogel-based formulation, UGN-102 is designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-102 is delivered to patients using a standard urinary catheter in an outpatient setting by a trained healthcare professional. UroGen completed the NDA submission for UGN-102 in August 2024, ahead of schedule. UroGen anticipates potential FDA approval in early 2025 if the NDA is accepted for filing by the FDA and priority review is granted.

About UGN-103 and UGN-104

UGN-103 and UGN-104 are innovative mitomycin formulations in development by UroGen for the treatment of LG-IR-NMIBC and LG-UTUC, respectively. UGN-103 aims to streamline manufacturing and reconstitution processes while providing intellectual property coverage until December 2041; it utilizes UroGen's *RTGel*® technology for prolonged mitomycin exposure. UGN-104, also leveraging *RTGel*® technology, is designed for treating low-grade upper tract urothelial cancer and is anticipated to enter Phase 3 trials in early 2025, offering a non-surgical treatment option with similar intellectual property protection.

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 LG-UTUC and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with low-grade non-muscle invasive bladder cancer are designed to ablate tumors by non-surgical means. UroGen is headquartered in Princeton, NJ with operations in Israel. To learn more, visit www.urogen.com or follow us on X (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 91 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.

Further information on the company can be found online at www.medac-group.com.

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: anticipated intellectual property protection; the potential for UGN-103 and UGN-104 to combine UroGen's *RTGel*® technology with medac's proprietary formulation to introduce new non-surgical treatment options for LG-IR-NMIBC and LG-UTUC, respectively; the belief that the combination of UroGen's *RTGel*® technology with medac's proprietary formulation could provide several advantages related to production, cost, supply, and product convenience; the timing for the planned Phase 3 trial of UGN-103 and UGN-104 and the potential approval of both drug candidates; the anticipated approval of UGN-102 and the timing thereof; the potential for UGN-102 to introduce a new non-surgical treatment option for LG-IR-NMIBC; 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; and other statements that are not historical fact. Words such as "anticipate," "believe," "could," "if," "intend," "plan," "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: the anticipated advantages of UGN-103 and UGN-104 have not yet been demonstrated or achieved, as applicable, and it is possible one or more of these anticipated advantages will not be realized; the timing and success of clinical trials and potential safety and other complications thereof; unforeseen delays that may impact the timing of initiating and progressing clinical trials, reporting data and initiating product launches; the ability to obtain regulatory approval within the timeframe expected, or at all; even if an NDA for UGN-102 is accepted for filing by the FDA, there is no guarantee that such NDA will be given priority review or that such NDA will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; the ability to maintain regulatory approval; the ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGel* technology; 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 13, 2024 (which is available at www.sec.gov), 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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