UroGen Announces Results from ATLAS Showing Robust UGN-102 Durability of Response in New and Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer at AUA 2024

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- **New and Recurrent Patients Treated with UGN-102 Achieved Similar Durability of Response Rates (DOR) at 12 months**

PRINCETON, N.J--(BUSINESS WIRE)--May 4, 2024-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced results from a new analysis of the ATLAS trial, which estimates using Kaplan Meier methods the probabilities of remaining in complete response for both new and recurrent low-grade intermediate-risk non- muscle invasive bladder cancer (LG-IR-NMIBC) patients following treatment with investigational drug UGN-102 as primary therapy, with or without subsequent transurethral resection of the bladder tumor (TURBT) at 3 months.

"These compelling findings shed light on the potential of UGN-102 as a nonsurgical primary treatment for low-grade intermediate-risk bladder cancer," said William Huang, M.D., Urologic Oncologist, Professor and Vice Chair of Urology, NYU Grossman School of Medicine. "These data are an encouraging step forward in addressing the broad spectrum of LG-IR-NMIBC and potentially curbing the high rates of disease recurrence associated with it."

In the Phase 3 ATLAS study, 282 patients with new or recurrent LG-IR-NMIBC were randomized to primary treatment with UGN-102 ± TURBT or TURBT alone. In the overall study population, Disease Free Survival (DFS) and DOR favored primary treatment with UGN-102 ± TURBT compared to TURBT alone. Complete response (CR) rates at the 3-month disease assessment were similar in both arms. While DFS and DOR rates were previously shared for both arms of the study, these are the first data specifically looking at the rates among new and recurrent patients within the UGN-102 ± TURBT arm. In this analysis using Kaplan Meier methods, DOR at 12 months after achieving CR at 3 months was 87.5% and 69.1% in new and recurrent patients, respectively. Also, patients achieved similar probabilities of DFS rates for UGN-102 at 15 months from randomization (77.4% and 63.2% in new and recurrent patients, respectively).

"These insightful data underscore the potential of UGN-102 impacting the treatment landscape for LG-IR-NMIBC," said Mark Schoenberg, M.D., Chief Medical Officer, UroGen. "Our aim is for UGN-102 to emerge as a non-surgical option for LG-IR-NMIBC, potentially sparing patients from the complexities and burdens associated with repetitive surgeries, including their inherent risks, side effects, and substantial impact on both individuals and healthcare systems."

Topline data from both the ATLAS trial and the Phase 3 ENVISION trial were initially shared in July of 2023. Twelve-month DOR data from the pivotal Phase 3 ENVISION trial are expected in June 2024.

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. Assuming positive findings from the durability of response endpoint from the ENVISION Phase 3 study, UroGen anticipates completing its New Drug Application (NDA) submission for UGN-102 in September 2024 with a potential U.S. Food and Drug Administration (FDA) decision as early as the first quarter of 2025.

About Non-Muscle Invasive Bladder Cancer (NMIBC)

In the U.S. bladder cancer is the second most common urologic cancer in men. LG-IR- NMIBC represents approximately 22,000 newly diagnosed bladder cancer patients each year and an estimated 60,000 recurrences annually among patients diagnosed from previous years. Bladder cancer primarily affects older populations with the median age of diagnosis 73 years and an increased risk of comorbidities. Guideline recommendations for the management of NMIBC include TURBT as the standard of care (SOC). 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.

About ATLAS

ATLAS was a global, open-label, randomized controlled Phase 3 trial designed to assess the efficacy and safety of UGN-102, with or without TURBT, vs. TURBT alone in patients diagnosed with LG-IR-NMIBC. The trial enrolled 282 patients in clinical sites in the U.S., Europe and Israel. Patients were randomized 1:1 to either UGN-102 or TURBT. Patients in the UGN-102 arm were treated with six weekly intravesical instillations of UGN-102. At the 3-month time point, patients were assessed for response. Patients who demonstrated a complete response to either UGN-102 or TURBT, were assessed for long-term duration of response. Patients who demonstrated presence of persistent disease at 3-months, in either arm, underwent a TURBT and continued for long-term follow-up for evidence of recurrence. The primary endpoint of the study is disease-free survival. Learn more about the ATLAS trial at www.clinicaltrials.gov (NCT04688931).

About ENVISION

The Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 (mitomycin) for intravesical solution as primary chemoablative therapy in patients with LG-IR-NMIBC. The Phase 3 ENVISION trial completed target enrollment with approximately 240 patients across 56 sites. Study participants received six once-weekly intravesical instillations of UGN-102. The primary endpoint evaluated the CR rate at the 3-month assessment after the first instillation, and the key secondary endpoint will evaluate durability over time in patients who achieved a CR at the 3-month assessment. Based on discussions with the FDA, and assuming positive findings, UroGen anticipates submitting

an NDA for UGN-102 in September 2024. 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 investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with 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.

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 of UGN-102 as a nonsurgical primary treatment for low-grade intermediate-risk bladder cancer and to potentially curb the high rates of disease recurrence associated with, and impact the treatment landscape for, LG-IR-NMIBC, including potentially sparing patients from the complexities and burdens associated with repetitive surgeries and their inherent risks, side effects and impact on individuals and healthcare systems; the Phase 3 ENVISION trial, including the expected release of data in June 2024; UroGen's plans to complete its NDA submission for UGN-102 in September 2024 if DOR endpoint data from the Phase 3 ENVISION trial is positive, with a potential FDA decision as early as the first quarter of 2025; the estimated patient population 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. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: results from ATLAS and this pre-specified analysis may not be indicative of results that may be observed in the future; findings from the DOR endpoint from the Phase 3 ENVISION trial may not be positive, and in such event, UroGen's NDA pathway could be negatively impacted; even if DOR endpoint data from the Phase 3 ENVISION trial are positive, there is no guarantee that the current clinical development plan for UGN-102 will ultimately support the submission of an NDA; even if an NDA for UGN-102 is accepted by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; potential safety and other complications from UGN-102; unforeseen delays that may impact the timing of progressing clinical trials and reporting data; the ability to obtain regulatory approval within 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; complications associated with commercialization activities; the labeling for any approved product; competition in UroGen's industry; the scope, progress and expansion of developing and commercializing UroGen's product candidates; the size and the growth of the market(s) for UroGen's product and product candidates, the rate and degree of market acceptance thereof vis-à-vis alternative therapies; UroGen's ability to attract or retain key management, members of its board of directors and personnel; UroGen's *RTGel* technology may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates UroGen's *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 Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 14, 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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