UroGen will Present Scientific Advances in Bladder Cancer at the Annual Meeting of the Society of Urologic Oncology

November 13, 2023

- *Results from the pivotal Phase 3 ENVISION trial studying primary chemoablation with UGN-102 (mitomycin) for intravesical solution in patients with recurrent low-grade intermediate-risk non-muscle-invasive bladder cancer (LG-IR-NMIBC) will be presented as a late-breaking oral presentation*
- *The Phase 3 ATLAS trial comparing the efficacy and safety of intravesical chemoablation with UGN-102 with or without subsequent TURBT, to TURBT alone in patients with LG-IR-NMIBC will be presented in a digital poster session*

PRINCETON, N.J.--(BUSINESS WIRE)--Nov. 13, 2023-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing novel solutions that treat urothelial and specialty cancers, will highlight data from two key Phase 3 trials evaluating UGN-102, an investigational treatment in development for LG-IR-NMIBC at the 2023 Society of Urologic Oncology (SUO) annual meeting, November 28-December 1 in Washington D.C. These data presentations further UroGen's mission of developing and commercializing innovative treatments for urothelial and specialty cancers that provide patients with novel non-surgical options to fulfill the unmet needs that exist with current standards of care.

"The ATLAS and ENVISION Phase 3 clinical trials broaden our understanding of potentially using a new approach to treat LG-IR-NMIBC," says Mark Schoenberg, M.D., Chief Medical Officer of UroGen. "We're particularly excited that the SUO selected the ENVISION study as one of only two late-breaking trials designated for oral presentations, which we believe further reinforces its potential in advancing bladder cancer treatment. We are optimistic for what the future may hold for LG-IR-NMIBC patients who suffer from this highly prevalent and recurrent disease."

Key highlights of UGN-102 data accepted by SUO:

Abstract Title	Presentation Details	
Primary chemoablation for recurrent low-grade intermediate risk (LG IR) NMIBC: The ENVISION trial	Podium Oral Presentation: Urothelial Cancer Session I Thursday, Nov 30th, 12:04 p.m. – 12:09 p.m. EST *Abstract available day of presentation	Presenter: Sandip Prasad, M.D. Morristown Medical Center/Atlantic Health System and Garden State Urology, Morristown, NJ
Treatment of low-grade intermediate risk non-muscle invasive bladder cancer with UGN-102 ± transurethral resection of bladder tumor (TURBT) compared to TURBT monotherapy: the Phase 3 ATLAS trial	Poster #132 Poster Available: Thursday, Nov 30th, 2:15 p.m. - 3:15 p.m. EST	Presenter: Sandip Prasad, M.D. Morristown Medical Center/Atlantic Health System and Garden State Urology, Morristown, NJ

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 submitting an NDA for UGN-102 in 2024.

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. JELMYTO® (mitomycin) for pyelocalyceal solution 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. Visit www.urogen.com to learn more or follow us on 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 for UGN-102 to introduce a new non-surgical treatment option for LG-IR-NMIBC and advance bladder cancer treatment; optimism for the future of LG-IR-NMIBC patients; the anticipated release of durability of response endpoint data from the ENVISION Phase 3 study; UroGen's plans to submit an NDA for UGN-102 and the expected timing thereof; and 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: preliminary results may not be indicative of results that may be observed in the future; the timing and success of clinical trials and potential safety and other complications thereof; 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; there is no guarantee that the current clinical development plan for UGN-102 will ultimately support submission of an NDA, notwithstanding the current agreement with the FDA; 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; the ability to maintain regulatory approval; 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 growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; UroGen's ability to attract or retain key management, members of the 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 RTGel technology; 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 September 30, 2023, filed with the SEC on November 14, 2023 (which is available at http://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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