UroGen Announces Start of Pivotal Single-Arm Phase 3 Trial for UGN-102, an Investigational Non-Surgical Treatment for Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer

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-- ENVISION Study Design Similar to Successful UGN-102 Phase 2b OPTIMA II Trial --

PRINCETON, N.J.--(BUSINESS WIRE)--Feb. 3, 2022-- UroGen Pharma Ltd. (Nasdaq: URGN), a biopharmaceutical company dedicated to building and commercializing novel solutions that treat urothelial and specialty cancers, today announced the initiation of its Phase 3 ENVISION study of UGN-102 (mitomycin) for intravesical solution, in patients with low-grade, intermediate-risk non-muscle invasive bladder cancer (NMIBC).

ENVISION is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 as primary chemoablative therapy in patients with low-grade, intermediate-risk NMIBC. The study design is similar to the Phase 2b OPTIMA II study in that patients will have the same clinical characteristics, treatment regimen, assessment, and qualitative follow up but with different endpoints. ENVISION is expected to enroll approximately 220 patients across 90 sites. Based on discussions with the U.S. Food and Drug Administration (FDA), and enrollment expected by end of 2022, assuming positive findings, UroGen anticipates submitting a New Drug Application (NDA) for UGN-102 in 2024.

“The start of the ENVISION trial marks the final phase of validating primary chemoablation for the treatment of recurrent intermediate risk NMIBC,” said Sandip Prasad, Urologist, Atlantic Health System, Morristown Medical Center, NJ, and lead study investigator for the ENVISION trial. “This study is designed to support the clinical potential of UGN-102 as a new treatment for patients that are under-served by the current standard of care, including those patients at risk for recurrence and those that are unwilling or unable to endure surgery or anesthesia.”

For the new Phase 3 trial, study participants will receive 6 once-weekly intravesical instillations of UGN-102. The planned primary endpoint is the complete response rate at three months after the first instillation, and the key secondary endpoint will be durability over time in patients who achieve complete response at the three-month assessment.

“We have achieved consistent results with similar study designs in the past and believe that it increases our probability for technical and regulatory success for UGN-102 in patients with low-grade, intermediate-risk NMIBC,” added Mark Schoenberg, Chief Medical Officer, UroGen. “We look forward to reporting data from ATLAS and acquiring new scientific evidence from ENVISION as we continue to explore the potential benefits of chemoablation in other types of bladder cancer, including high-grade disease and other specialty cancers.”

About LG IR NMIBC

Out of the 80,000 estimated cases of bladder cancer per year in the U.S., approximately 35,000 are low-grade NMIBC patients comprised of both low-risk (approximately 15,000) and intermediate risk (approximately 20,000). These patients face a future of recurrence and additional surgeries.

Recurrence in low-grade intermediate-risk NMIBC is pervasive and often underestimated. In patients who recur, approximately 68 percent will experience two or more recurrence episodes throughout the course of their disease, a high and frequent rate in contrast to other non-metastatic cancers.

Currently, the only effective primary treatment available is a surgical procedure known as transurethral resection of bladder tumor, or TURBT. Every time TURBT is performed it imposes more burden and serious risks on patients. Approximately 25 percent of patients are not appropriate for TURBT, whether due to physical factors such as age and comorbidities or an unwillingness to undergo surgery.

About UroGen Pharma Ltd.

UroGen is a biopharmaceutical company dedicated to building novel 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 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. UroGen’s first commercial product, 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 statements regarding the ENVISION study and our enrollment expectations therefor, the timing of the planned NDA for UGN-102, and our belief that the study design for ENVISION will increase the probability for technical and regulatory success. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: clinical trial site initiation and enrollment challenges that may impact the expected timing and progress of our clinical trials, including challenges related to the ongoing COVID-19 pandemic; results from prior clinical trials may not be indicative of results that may be observed in ongoing or future clinical trials; the timing and success of clinical trials and potential complications thereof; UroGen’s ability to attract or retain key management, members of the board of directors and personnel; and any negative effects on UroGen’s business, commercialization and product development plans caused by or associated with COVID-19. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen’s Form 10-Q filed with the SEC on November 15, 2021 and other filings that UroGen makes with the SEC from time to time (which are 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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