First Patient Dosed in UroGen Pharma's Home Instillation Study of UGN-102 in Patients with Low-Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer (LG IR-NMIBC)

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Study explores opportunity to shift from clinic to home instillation of this promising non-surgical treatment

Potential to transform care and access to treatment for this growing patient population

PRINCETON, N.J.--(BUSINESS WIRE)--Dec. 21, 2021-- UroGen Pharma Ltd. (Nasdaq: URGN), a biopharmaceutical company dedicated to building and commercializing novel solutions that treat urothelial and specialty cancers, today announced that the first patient has received their first dose in its home instillation study of UGN-102 in patients with low-grade, intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).

The objective of this Phase 3b study, which aims to enroll up to ten patients across four centers, is to demonstrate whether UGN-102 can be administered at home by a qualified home health professional, avoiding the need for repeated visits to a healthcare setting for instillation.

"The ease of UGN-102 instillation is of great benefit to these patients who are generally older, suffer from multiple comorbidities, and often rely on caregivers to drive them to medical appointments," said Mark Schoenberg, M.D., Chief Medical Officer of UroGen. "Home instillation is especially convenient for the patient and less burdensome for caregivers as they navigate persistent challenges caused by repeated medical appointments. We look forward to demonstrating the versatility of UGN-102 in this study as we prepare to initiate the single-arm, pivotal Phase 3 ENVISION Study of UGN-102 in early 2022."

Patients in the ongoing Phase 3b study will receive six once-weekly intravesical instillations of UGN-102. The initial treatment visit will occur at the investigative site and instillation will be performed by a qualified physician. Treatment visits two to six will take place at the patient's home and instillation will be performed by a properly trained and qualified home health professional. The primary endpoint of the study is the incidence of treatment-emergent adverse events (TEAEs), serious TEAEs, TEAEs of special interest, discontinuations from at home study treatment, and clinically significant abnormalities in laboratory tests (hematology, serum chemistry, and urinalysis).

About UGN-102 (mitomycin for intravesical solution)
UGN-102 consists of mitomycin and sterile hydrogel (a proprietary thermally responsive gel) that is used to reconstitute mitomycin before instillation. The reverse thermal properties of UGN-102 allow for local administration of mitomycin as a liquid, with subsequent conversion to a semi-solid gel depot following instillation into the bladder.

About LG-IR-NMIBC
With 80,000 estimated cases of bladder cancer per year, 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 LG-IR-NMIBC is a pervasive and often underestimated problem. In patients who recur, it is estimated that 68 percent will experience two or more recurrence episodes throughout the course of their disease, a considerably 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 the bladder (TURBT). The more the procedure is performed, the more it imposes burden and serious risks on patients. Research shows that 25 percent of patients are not appropriate for TURBT due to physical factors such as age and comorbid conditions or an unwillingness to undergo surgery. Major challenges exist with the current standard of care and these patients deserve a new primary, non-surgical treatment option.

About UroGen Pharma Ltd.
UroGen is a biopharmaceutical company dedicated to building novel solutions that treat specialty cancers and urologic diseases 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, without limitation, statements regarding: the design and objectives of our Phase 3b study of UGN-102; the expected versatility and other benefits of UGN-102 in the home setting, including the potential to transfer care and access to treatment; our planned single-arm, pivotal Phase 3 ENVISION Study of UGN-102 and the timing thereof; and potential future growth in the patient population for UGN-102. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: clinical trial enrollment challenges that may impact the expected timing of our ongoing and planned clinical trials, including challenges related to the ongoing COVID-19 pandemic; the timing and success of clinical trials and potential safety and other complications thereof; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with commercialization activities, including complications resulting from the ongoing COVID-19 pandemic; the labeling for any approved product; 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; 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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