UroGen Announces First Patient Dosed in Phase 1 Trial of UGN-501, an Investigational Next-Generation Oncolytic Virus for Non-Muscle Invasive Bladder Cancer

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- Phase 1 clinical trial to evaluate local intravesical administration of UGN-501
- UGN-501 is a differentiated investigational next-generation oncolytic virus designed to combine direct tumor cell destruction with anti-tumor immune activation

PRINCETON, N.J., Nov. 02, 2026 (GLOBE NEWSWIRE) -- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that the first patient was dosed with UGN-501, a next-generation investigational oncolytic virus. The Phase 1 trial will evaluate the safety, tolerability, and feasibility of intravesical administration of UGN-501.

“The first patient dosed with UGN-501 marks an important step in advancing this investigational therapy from nonclinical research into clinical evaluation,” said Mark Schoenberg, M.D., Chief Medical Officer of UroGen. “We can now begin to understand its safety and tolerability in patients with NMIBC and generate insights to guide its continued development. This progress brings us closer to our goal of expanding treatment options for patients with bladder cancer.”

The Phase 1, open-label, dose-escalation trial is designed to evaluate the safety, tolerability and pharmacokinetics of intravesically administered UGN-501 and determine the recommended Phase 2 dose in adults with recurrent non-muscle invasive bladder cancer (NMIBC), including high-grade Ta/T1 disease and/or carcinoma in situ (CIS), or low-grade Ta/T1 disease. Before treatment, all visible papillary tumors must be resected and obvious areas of CIS fulgurated. Participants will receive an aqueous formulation of UGN-501 through six once-weekly intravesical instillations during a 12-week induction period. Participants with no evidence of disease at week 12 may proceed to maintenance treatment consisting of three once-weekly instillations administered quarterly from month three through month 12, or until disease recurrence, disease progression or death, whichever occurs first, with a safety follow-up visit at month 15. For more information about the Phase 1 trial, go to ClinicalTrials.gov at **NCT07725796.**

In parallel with the Phase 1 trial, UroGen is conducting nonclinical studies exploring the formulation of UGN-501 in its proprietary *RTGel*® technology. The formulation being evaluated in the current Phase 1 trial is aqueous and does not contain *RTGel*.

NMIBC continues to present significant clinical challenges, particularly among patients whose disease recurs following standard treatment. Despite available therapies, recurrence rates remain substantial, underscoring the need for novel bladder-sparing therapeutic approaches. UroGen believes UGN-501's differentiated mechanism of action and local administration strategy may offer a promising new approach for addressing this unmet need.

About UGN-501

UGN-501 is an investigational, next-generation oncolytic virus being investigated for the treatment of non-muscle invasive bladder cancer (NMIBC). UGN-501 is designed to selectively replicate within tumor cells, resulting in direct tumor cell destruction and an anti-tumor immune response. The program is supported by nonclinical data demonstrating cytotoxic activity across a broad panel of bladder cancer cell lines representing multiple stages and grades of disease. While UGN-501 is initially being developed for bladder cancer, the Company believes UGN-501's underlying properties may have broader applicability across additional solid tumor indications and intends to evaluate future development opportunities based on emerging clinical and translational data.

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 our second product to treat adult patients with recurrent 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 (formerly 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 progress and plans for the Phase 1 clinical trial of UGN-501 in NMIBC; UroGen’s nonclinical studies exploring the formulation of UGN-501 in its proprietary *RTGel* technology; the design and potential benefits of UGN-501, including to selectively replicate within tumor cells, resulting in direct tumor cell destruction and an anti-tumor immune response, and its differentiated mechanism of action and local administration strategy potentially offering a promising new approach for addressing un unmet need; UGN-501’s potential for broader applicability across additional solid tumor indications; UroGen’s plans to evaluate future development opportunities for NMIBC based on emerging clinical and translational data; the belief that UGN-501 has several attributes that differentiate it from other oncolytic viruses; the potential of UroGen’s proprietary *RTGel* technology to improve therapeutic profiles of existing drugs or UGN-501 and UroGen’s sustained release technology making local delivery potentially more effective as compared to other treatment options. Words such as “believe,” “can,” “expect,” “intend,” “may,” “plan,” “potential,” “will,” or other words that convey uncertainty of future events or outcomes are used to identify these forward-looking statements. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: nonclinical results may not be indicative of results that may be observed in clinical trials; 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 other personnel;

UroGen's *RTGel* technology may not perform as expected, including when formulated with UGN-501; UroGen's financial condition and need for additional capital; and UroGen may not successfully develop and receive regulatory approval of a product candidate, including ones that incorporate *RTGel* technology. 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, 2026, filed with the SEC on August 5, 2026 (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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