UroGen Announces FDA Clearance of the IND for UGN-501, an Investigational Next-Generation Oncolytic Virus for Non-Muscle Invasive Bladder Cancer

July 8, 2026

- FDA clearance enables initiation of a planned Phase 1 clinical study evaluating local intravesical administration of UGN-501, with patient enrollment expected to begin in Q4 2026
- 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., July 08, 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 U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug application (IND) for UGN-501, a next-generation investigational oncolytic virus. The IND clearance enables initiation of a planned Phase 1 clinical study in patients with non-muscle invasive bladder cancer (NMIBC). The Phase 1 study is expected to begin in Q4 2026 and will evaluate the safety, tolerability, and feasibility of intravesical administration of UGN-501.

"Patients with non-muscle invasive bladder cancer continue to face a significant risk of disease recurrence despite available treatment options," said Mark Schoenberg, M.D., Chief Medical Officer of UroGen. "UGN-501 is an investigational next-generation oncolytic virus designed to selectively destroy tumor cells while generating an anti-tumor immune response. FDA clearance of the IND allows us to begin evaluating whether the encouraging nonclinical profile of UGN-501 can translate into a safe and meaningful therapeutic approach for patients with NMIBC. We look forward to initiating the Phase 1 study and advancing our efforts to develop innovative treatment options for patients with bladder cancer."

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 planned Phase 1 clinical study of UGN-501 in NMIBC and the expected timing for patient enrollment; the potential benefits of UGN-501, including to selectively target cancer cells while retaining potency, triggering an immune response, and minimizing systemic exposure; UGN-501's potential as a safe and meaningful therapeutic approach for patients with NMIBC and its 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 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: prior results may not be indicative of results that may be observed in the future; 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 other personnel; UroGen's *RTGel* technology may not perform as expected; UroGen's financial condition and need for additional capital; and UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *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 March 31, 2026, filed with the SEC on May 6, 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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