UroGen Pharma and MD Anderson Announce Strategic Research Collaboration to Advance Investigational Treatment for High-Grade Bladder Cancer

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Collaboration will focus on UGN-302 as an investigational treatment for high-grade non-muscle invasive bladder cancer

PRINCETON, N.J. & HOUSTON--(BUSINESS WIRE)--Jan. 13, 2021-- UroGen Pharma Ltd. (Nasdaq: URGN), a biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases, and The University of Texas MD Anderson Cancer Center today announced a strategic three-year collaboration agreement to advance combinatorial intravesical immunotherapy, which is delivered directly into the bladder, for the treatment of high-grade non-muscle invasive bladder cancer (HG-NMIBC). UroGen's approach involves the local delivery of potent immunomodulators (UGN-201, a TLR 7/8 agonist and UGN-301, an anti-CTLA-4 antibody). UGN-301, an immune checkpoint inhibitor, is delivered using UroGen's proprietary RTGel™ platform to increase dwell time, which has been shown to significantly improve the effectiveness of intravesical therapy.

"We are pleased to enter into this collaboration with MD Anderson and its immunotherapy platform, which brings unique translational and clinical expertise in immuno-oncology," said Mark Schoenberg, M.D., Chief Medical Officer of UroGen Pharma. "This agreement will help UroGen potentially bring next-generation immunotherapy to bladder cancer patients with a significant unmet need and limited clinical options other than bladder removal."

Under the agreement, MD Anderson and UroGen will collaborate on the design and conduct of non-clinical and clinical studies with oversight from a joint steering committee. UroGen will provide funding, developmental candidates, and other support.

UroGen's investigational candidates, UGN-201 and UGN-301, are being developed to ablate tumors by non-surgical means in the treatment of HG-NMIBC. Non-clinical data suggest treatment with the combination of UGN-201 and an anti-CTLA4 antibody, delivered using UroGen's proprietary RTGel platform, may result in improved survival and decreased tumor size.

"Immune checkpoint inhibitors have become important treatment options for many patients with bladder cancer, and we look forward to working with UroGen to advance new immunotherapy strategies with intravesical delivery," said James Allison, Ph.D., chair of Immunology, executive director of the immunotherapy platform and co-director of the Parker Institute for Cancer Immunotherapy at MD Anderson. "This novel delivery approach has the potential to limit the adverse events seen with systemic immunotherapy treatment while providing clinical benefit, which would represent a major advancement to patient care."

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.

About MD Anderson

The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 51 comprehensive cancer centers designated by the National Cancer Institute (NCI). MD Anderson is ranked No. 1 for cancer care in U.S. News & World Report's "Best Hospitals" survey. It has ranked as one of the nation's top two hospitals for cancer care since the survey began in 1990 and has ranked first 16 times in the last 19 years. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

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: the potential of UroGen's proprietary RTGel™ technology platform to improve therapeutic profiles of existing drugs; the ability of the collaboration agreement to potentially bring next-generation immunotherapy to bladder cancer patients with a significant unmet need and limited clinical options; the potential for treatment with the combination of UGN-201 and an anti-CTLA4 antibody, delivered using UroGen's proprietary RTGel platform, to result in improved survival and decreased tumor size; and the potential of immunotherapy strategies with intravesical delivery to limit the adverse events seen with systemic immunotherapy treatment while providing clinical benefit. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: 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; 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 9, 2020, 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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INVESTOR CONTACT:
Sara Blum Sherman
Head of Investor Relations
sara.sherman@urogen.com
609-467-4975

MEDIA CONTACT:
Eric Van Zanten
Head of Communications
eric.vanzanten@urogen.com
610-529-6219

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