



UroGen Advances Long-Term Growth Strategy by Acquiring a Next-Generation Investigational Oncolytic Virus (ICVB-1042) and Announces Multiple Strategic Research Collaborations

February 20, 2025

- ICVB-1042 is an Oncolytic Virus Engineered to Selectively Destroy Cancer Cells While Retaining Potency and Trigger a Robust Immune Response
- Strategic Research Collaborations Focused on Exploring the Potential of UroGen's Innovative RTGel[®] Technology to Enhance the Clinical Effectiveness of Multiple Immunotherapies
- Conference Call Webcast to be Held Today at 12:00 PM ET

PRINCETON, N.J.--(BUSINESS WIRE)--Feb. 20, 2025-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced expansion of its oncology pipeline portfolio through the acquisition of assets relating to a next-generation oncolytic virus ICVB-1042 from IconOVir Bio, Inc. (IconOVir). In addition, UroGen also announced that it has entered into multiple strategic research collaborations to explore the potential of its proprietary RTGel technology to enhance clinical effectiveness of multiple immunotherapies, including optimizing dwell time to improve treatment outcomes.

"UroGen's long-term growth strategy is built on advancing our uro-oncology pipeline, expanding our portfolio, and driving innovation in cancer treatment," said Liz Barrett, President and Chief Executive Officer of UroGen. "The acquisition of ICVB-1042, a next-generation investigational oncolytic virus, marks a significant milestone in our plan to develop novel, locally administered therapies for bladder cancer and other specialty cancers. This strategic investment underscores our commitment to identifying and advancing high-impact therapies that address critical unmet needs. Through targeted acquisitions and research collaborations, we are strengthening UroGen's leadership in oncology and laying the foundation for sustained innovation and growth."

The use of biological agents to treat bladder cancer has its roots in the development of Bacillus Calmette-Guérin (BCG) therapy. Much like BCG therapy, ICVB-1042 is being developed to activate the immune system within the tumor microenvironment, but unlike BCG therapy, ICVB-1042 has the potential to selectively destroy cancer cells while retaining potency and trigger a robust immune response. A fusion of potency and cancer cell destruction would mark a groundbreaking step forward, unlocking new possibilities in the fight against cancer.

"The treatment of bladder cancer has long been shaped by immunological approaches such as BCG therapy. UroGen now seeks to advance bladder cancer treatment with highly targeted, next-generation viral immunotherapies like ICVB-1042," said Mark Schoenberg, M.D., Chief Medical Officer of UroGen. "ICVB-1042 may represent an exciting leap forward, with several attributes we believe differentiate this asset from other oncolytic viruses. Supported by a robust non-clinical data package, we are eager to develop this investigational therapy as a potential new treatment in localized cancer."

Asset Purchase

On February 14, 2025, UroGen acquired certain assets of IconOVir, including product candidate ICVB-1042, and assumed certain liabilities and obligations of IconOVir arising under certain acquired contracts. As consideration for the assets, UroGen issued IconOVir 374,843 of its ordinary shares (representing a value of approximately \$4.0 million based on 30-day VWAP), agreed to pay IconOVir a one-time payment of \$15.0 million in cash upon the achievement of a cumulative aggregate worldwide net sales milestone for all products, including combination products, that incorporate or comprise ICVB-1042 (ICVB Products), and agreed to pay IconOVir a certain low, single-digit percentage royalty on a ICVB Product-by-ICVB Product basis on annual worldwide net sales of such ICVB Product.

Conference Call & Webcast Information

Members of UroGen's management team will host a live conference call and webcast today at 12:00 PM ET to discuss the Company's long-term growth strategy. The live webcast can be accessed by visiting the Investors section of the Company's website at <http://investors.UroGen.com>. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast.

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 investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with LG-IR-NMIBC are designed to ablate tumors by non-surgical means. UroGen is headquartered in Princeton, NJ with operations in Israel. To learn more, visit www.UroGen.com to learn more or follow us on X (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: UroGen's long-term growth strategy; UroGen's targeted acquisitions and research collaborations strengthening UroGen's leadership in oncology and laying the foundation for sustained innovation and growth; the focus of UroGen's strategic research collaborations; the potential of ICVB-1042 to selectively target cancer cells while retaining potency, triggering an immune response, and minimizing systemic exposure; the belief that ICVB-1042 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," "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 September 30, 2024, filed with the SEC on November 6, 2024 (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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