UroGen Secures Exclusive License from medac GmbH to Develop a Next-Generation Novel Mitomycin-Based Formulation for Urothelial Cancers

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PRINCETON, N.J.--(BUSINESS WIRE)--Jan. 17, 2024-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing novel solutions that treat urothelial and specialty cancers, today announced a licensing agreement with medac GmbH to develop a next-generation novel mitomycin-based formulation for urothelial cancers.

UGN-103, UroGen's RTGel ® technology combined with medac's licensed mitomycin, is a next-generation formulation that is planned to follow the anticipated U.S. Food and Drug Administration approval and launch of UGN-102. UGN-103 is expected to provide advantages related to production, cost, supply, and product convenience if approved. UroGen plans to initiate a Phase 3 study in 2024 to explore the safety and efficacy of UGN-103 in LG-IR-NMIBC.

"The strategic alliance with medac fortifies our commitment to continuously innovate novel, non-surgical treatments for patients with urothelial cancers, including LG-IR-NMIBC," said Liz Barrett, President and CEO of UroGen. "The 80 mg formulation of mitomycin from medac is specifically designed to be mixed with our RTGel® technology, which may provide advantages for patients looking for non-surgical treatments for urothelial cancer. With medac's intellectual property protection for this next-generation mitomycin formulation lasting until June 2035 and our pending U.S. patent applications, we foresee potential intellectual property protection until December 2041."

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin, currently in Phase 3 development for the treatment of LG-IR-NMIBC. Utilizing UroGen's proprietary RTGel ® technology, a sustained release, hydrogel-based formulation, UGN-102 is designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. UGN-102 is delivered to patients using a standard urinary catheter in an outpatient setting. Assuming positive findings from the durability of response endpoint from the ENVISION Phase 3 study, UroGen anticipates submitting a New Drug Application (NDA) for UGN-102 in 2024 and an FDA decision in 2025.

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 LG-UTUC 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 X (Twitter), @UroGenPharma.

About medac GmbH

medac is a privately-owned German pharmaceutical company with sites in Wedel and Tornesch. medac's medicinal products are used worldwide to help doctors and patients manage acute and chronic diseases in the fields of oncology and haematology, urology, and autoimmune diseases. medac also develops and distributes specialist diagnostic systems. Since 1970, medac has been committed to its approach of uniting therapeutic and diagnostic products under one roof. Further information on the company and its products can be found online at www.medac.de.

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 anticipated approval and launch of UGN-102; the timing for the planned Phase 3 trial of UGN-103 and the potential approval of UGN-103; the potential advantages of UGN-103; anticipated intellectual property protection; the anticipated submission of an NDA for UGN-102 and the timing thereof; the anticipated timing for an FDA decision on the UGN-102 NDA; the potential for UGN-102 to introduce a new non-surgical treatment option for LG-IR-NMIBC; and 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 "anticipate," "believe," "could," "expect," "plan," "potential," "will," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: preliminary results may not be indicative of results that may be observed in the future; the timing and success of clinical trials and potential safety and other complications thereof; unforeseen delays that may impact the timing of progressing clinical trials, reporting data and initiating product launches; the ability to obtain regulatory approval within the timeframe expected, or at all; the findings from the durability of response endpoint from the ENVISION Phase 3 study may not be positive, and in such event, our NDA pathway could be negatively impacted; even if the durability of response endpoint data from the ENVISION Phase 3 study are positive, there is no guarantee that our NDA for UGN-102 will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; 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; UroGen's pending patent applications may not be successful and in such event the duration of our intellectual property protection would be more limited; risks related to our and our licensors' ability to protect our respective patents and other intellectual property; the size and growth of the market(s) for our product and product candidates 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; UroGen's RTGel technology may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates RTGel technology; and UroGen's financial condition and need for additional capital in the future. 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, 2023, filed with the SEC on November 14, 2023 (which is 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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