



UroGen Announces FDA Acceptance of Investigational New Drug Application for UGN-103, a Next Generation Mitomycin-Based Formulation for Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer

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- UroGen plans to initiate a Phase 3 study to explore the safety and efficacy of UGN-103 in 2024
- Anticipated advantages include a new 80 mg mitomycin dosage strength that may considerably shorten the manufacturing process, simplify the reconstitution procedure, and potentially extend intellectual property protection until as late as December 2041

PRINCETON, N.J.--(BUSINESS WIRE)--Apr. 15, 2024-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing novel solutions that treat urothelial and specialty cancers, today announced the U.S. Food and Drug Administration (FDA) accepted the Company's Investigational New Drug (IND) application for UGN-103, a next-generation novel mitomycin-based formulation for low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC).

The UGN-103 formulation uses UroGen's RTGel[®] platform technology, a proprietary sustained-release, reverse-thermal hydrogel that can improve the therapeutic profiles of existing drugs. UGN-103 is anticipated to provide several 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 for the treatment of LG-IR-NMIBC, a highly recurrent disease.

"We are delighted by the FDA's acceptance of our IND for UGN-103, marking a significant step forward in our mission," said Liz Barrett, President and Chief Executive Officer of UroGen. "We eagerly anticipate commencing a clinical trial with UGN-103 this year, as we strive to continually advance and develop treatments for patients with high unmet need."

UGN-103 is planned to follow the anticipated FDA approval and launch of UGN-102 (mitomycin) for intravesical solution for LG-IR-NMIBC. UroGen intends to complete the rolling new drug application (NDA) submission for UGN-102 in September 2024, with a potential FDA decision as early as the first quarter of 2025 if priority review is granted by FDA.

About UGN-103

UGN-103 (mitomycin) for intravesical solution is an innovative drug formulation of mitomycin being developed for the treatment of LG-IR-NMIBC. UroGen plans to initiate a Phase 3 study to explore the safety and efficacy of UGN-103 in 2024. Anticipated advantages of UGN-103 include a new 80 mg mitomycin dosage strength that may considerably shorten the manufacturing process, simplify the reconstitution procedure, and potentially extend intellectual property protection until as late as December 2041. UGN-103 will utilize UroGen's proprietary RTGel[®] technology, a sustained release, hydrogel-based formulation designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means.

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 an NDA for UGN-102 in September 2024 and a potential FDA decision as early as the first quarter of 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. To learn more, visit www.urogen.com 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: the belief that UGN-103, if approved, will provide several advantages related to production, cost, supply, and product convenience; UroGen's pending intellectual property protection for UGN-103 potentially extending until December 2041; UroGen's plans to initiate Phase 3 studies to explore the safety and efficacy of UGN-103 in 2024; the anticipated timing for completing a submission of an NDA to the FDA for UGN-102 and the potential FDA decision; 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," "intend," "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: the anticipated advantages of UGN-103 have not yet been demonstrated or achieved, as applicable, and it is possible one or more of these anticipated advantages will not be realized; 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, UroGen's 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 the current clinical development plan for UGN-102 will ultimately support submission of an NDA; even if an NDA for UGN-102 is accepted by the FDA, there is no guarantee that such NDA will be sufficient to support approval of UGN-102 on the timeframe expected, or at all; the ability to maintain regulatory approval; the ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights; 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) for UroGen's 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 Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 14, 2024 (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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