UroGen Initiates Submission of a Rolling NDA to the FDA for UGN-102

January 24, 2024

PRINCETON, N.J.--(BUSINESS WIRE)--Jan. 24, 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 submission of the Chemistry, Manufacturing, and Controls (CMC) section of the New Drug Application (NDA) for UGN-102 (mitomycin) for intravesical solution to the U.S. Food and Drug Administration (FDA).

"The submission of the CMC portion of the NDA for UGN-102 marks a significant milestone for UroGen and underscores our dedication to advancing innovative therapies for the benefit of individuals grappling with low-grade, intermediate-risk non-muscle invasive bladder cancer," said Liz Barrett, President and CEO, UroGen. "We look forward to working closely with the FDA throughout the review process and remain steadfast in our commitment to address unmet medical needs in the uro-oncology space and advance patient care."

The objective of the rolling NDA for UGN-102 is to facilitate early engagement with the FDA, and a more efficient and timely review of the NDA. Based on its agreement with the FDA, UroGen will complete the submission of the rolling NDA for UGN-102 in 2024 with a potential FDA decision as early as the first quarter of 2025.

The CMC section of a regulatory submission typically includes information about the drug product such as its physicochemical properties, formulation, methods of manufacture, specifications, stability data, and analytical methods used to test the product.

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 low-grade, intermediate-risk, non-muscle invasive bladder cancer (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 completing its NDA submission for UGN-102 in 2024 with 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 low-grade upper tract urothelial cancer 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.

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 completion of the NDA submission for UGN-102 and the timing thereof; the timing for an FDA decision on UGN-102; the potential for UGN-102 to introduce a new non-surgical treatment paradigm 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," "assume," "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 and reporting data; 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 the current clinical development plan for UGN-102 will ultimately support submission of an NDA, notwithstanding the current agreement with the FDA; 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; 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 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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Source: UroGen Pharma Ltd.