UroGen Announces FDA Advisory Committee for UGN-102, an Investigational Treatment for Recurrent Low-Grade Intermediate-Risk Non-Muscle Invasive Bladder Cancer

May 7, 2025

PRINCETON, N.J.--(BUSINESS WIRE)--May 7, 2025-- UroGen (NASDAQ: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, today announced that the U.S. Food and Drug Administration (FDA) has scheduled an Oncologic Drugs Advisory Committee (ODAC) meeting on May 21, 2025 to review the new drug application (NDA) for UGN-102 (mitomycin) for intravesical solution, an investigational treatment for recurrent LG-IR-NMIBC.

The ODAC meeting will provide an opportunity for independent clinicians and other experts to evaluate the UGN-102 data and make a recommendation to the FDA as to whether the NDA should be approved and under what conditions. The FDA carefully considers the advice of the Advisory Committee, but is not bound by its recommendations. The FDA has stated in its correspondence to the Company that they intend to complete their review in time to meet the Prescription Drug User Fee Act (PDUFA) target action date of June 13, 2025.

“We are excited to discuss our data with the Advisory Committee and broader medical community as we continue our mission to bring innovative solutions to patients suffering from bladder cancer,” said Liz Barrett, President and Chief Executive Officer of UroGen. “We believe UGN-102 represents a meaningful advancement for patients facing the recurrent and challenging nature of LG-IR-NMIBC, and we look forward to the opportunity to discuss its potential.”

UGN-102 is in development as a therapeutic option for patients with recurrent LG-IR-NMIBC, a condition for which there are no FDA-approved drugs. The NDA is supported by results from the pivotal Phase 3 ENVISION trial which demonstrated a 79.6% complete response (CR) rate at 3 months after first instillation of UGN-102, and duration of response of 82.5% at 12 months after 3-month CR by Kaplan-Meier analysis.

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 recurrent 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 by a trained healthcare professional. UroGen completed the NDA submission in August, ahead of schedule. The FDA accepted the NDA for UGN-102, scheduled an ODAC meeting for May 21, 2025, and assigned a PDUFA target action date of June 13, 2025.

About Low-Grade Non-Muscle Invasive Bladder Cancer (NMIBC)

In the U.S., bladder cancer is the second most common urologic cancer in men and primarily affects older populations with increased risk of comorbidities, with the median age of diagnosis being 73 years. More specifically, LG-IR-NMIBC represents approximately 23,000 newly diagnosed bladder cancer patients each year and an estimated 59,000 recurrences annually among patients diagnosed in previous years. Guideline recommendations for the management of NMIBC include trans-urethral resection of bladder tumor (TURBT) as the standard of care. Up to 70% of NMIBC patients experience at least one recurrence and LG-IR-NMIBC patients are even more likely to recur and face repeated TURBT procedures.

About UroGen

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 carcinoma and investigational treatment UGN-102 (mitomycin) for intravesical solution for patients with recurrent 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 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-102 represents a meaningful advancement for patients facing the recurrent and challenging nature of LG-IR-NMIBC; the results from the pivotal Phase 3 ENVISION trial providing evidence of UGN-102's potential to become an effective and durable treatment option for patients with recurrent LG-IR-NMIBC; statements related to UroGen’s UGN-102 NDA submission, scheduled Advisory Committee meeting, and expected PDUFA target action date; the estimated annual U.S. patient population and demographics for LG-IR-NMIBC; 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. 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; even though the NDA for UGN-102 has been accepted for filing 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 FDA’s scheduling of an Advisory Committee meeting should not be relied on as an indication that UGN-102 will ultimately be approved, and there are multiple examples of the FDA scheduling advisory committee meetings for product candidates that were not ultimately approved; the outcome of the Advisory Committee is uncertain and it is possible that the Advisory Committee will have an adverse or split recommendation with respect to UGN-102; even if the Advisory Committee recommends the approval of UGN-102, the FDA is not bound by the Advisory Committee’s recommendation; the PDUFA target action date may be delayed due to various factors outside UroGen’s control; 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; 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-K for the year ended December 31, 2024, filed with the SEC on March 10, 2025 (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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