UroGen Completes Enrollment of Its Phase 3 Clinical Trial for UGN-102 in Development for Low-Grade, Intermediate-Risk, Non-Muscle Invasive Bladder Cancer (LG-IR-NMIBC)

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--If approved, UGN-102 would be the first non-surgical primary therapeutic to treat a subset of bladder cancer characterized by high recurrence rates and multiple surgeries

PRINCETON, N.J.--(BUSINESS WIRE)--Dec. 19, 2022-- UroGen Pharma Ltd. (Nasdaq: URGN), a biotech company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers, announced that the Phase 3 ENVISION study of investigational agent UGN-102 (mitomycin) for intravesical solution in development for the treatment of LG-IR-NMIBC is fully enrolled. The ENVISION study targeted enrollment of 220 patients across 90 sites and, assuming positive findings, UroGen anticipates submitting a New Drug Application (NDA) for UGN-102 in 2024.

“Completing enrollment for the ENVISION trial is a major milestone that brings us one step closer to validating chemoablation for the treatment of LG-IR-NMIBC,” said Sandip Prasad, M.D., M.Phil., Director of Genitourinary Surgical Oncology, Morristown Medical Center, Atlantic Health System, NJ, and lead study investigator for the ENVISION trial. “These patients are burdened with disease recurrences and repeat surgeries that take a toll on an elderly population who often have co-morbidities that increase the risks associated with surgery. If successful ENVISION has the potential to fundamentally change the way we treat these patients.”

ENVISION is a Phase 3, single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 as primary chemoablative therapy, in 220 patients with LG-IR-NMIBC from 90 sites. The design for the Phase 3 ENVISION trial is similar to the Phase 2b OPTIMA II trial in that the patient population will have similar clinical characteristics, receive the same treatment regimen and undergo the same efficacy and safety assessments and qualitative follow-up. Patients enrolled in ENVISION will receive six once-weekly intravesical instillations of UGN-102. The primary endpoint is the complete response rate at PDE (primary disease evaluation) which will typically occur within three months from the first instillation, and the key secondary endpoint will be durability of response in patients who achieve complete response.

“We are optimistic about the clinical potential of UGN-102 because ENVISION shares a similar approach to the successful OPTIMA II Phase 2b study,” said Mark Schoenberg, Chief Medical Officer, UroGen. “Also, our chemoablative treatment for low-grade upper tract urothelial cancer and UGN-102 uses our proprietary RTGel™ technology, and the urothelial lining in the bladder and upper tract is similar. If approved UGN-102 may offer additional advantages because it is instilled into the bladder via urethral catheter in an outpatient setting – a common procedure in most urologists’ offices.”

If approved UGN-102 has the potential to offer a simpler, minimally invasive, and non-surgical option to transurethral resection of bladder tumor (TURBT), as UGN-102 can be administered without the use of anesthesia or special equipment. UroGen’s first product and UGN-102 utilize mitomycin as their active pharmaceutical ingredient, although in a different ratio and both allow for local delivery and sustained exposure to mitomycin for up to six hours.

About LG-IR-NMIBC

Approximately 800,000 people are living with bladder cancer in the U.S., of that 80,000 suffer from LG-IR-NMIBC. Patients with LG-IR-NMIBC face a future of recurrence and additional surgeries. Currently, the only primary treatment available is a surgical procedure known as TURBT, which requires anesthesia. Every time TURBT is performed it may impose more burden and serious risks on patients, including pain, bleeding, infection and injury (including perforation).

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an investigational drug formulation of mitomycin 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 ENVISION Phase 3 study, UroGen anticipates submitting a New Drug Application (NDA) for UGN-102 in 2024. If approved, UGN-102 would be the first non-surgical primary therapeutic to treat a subset of bladder cancer characterized by high recurrence rates and multiple surgeries.

About UroGen Pharma Ltd.

UroGen is a biopharmaceutical company dedicated to building novel 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 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. UroGen’s first commercial product, 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 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 ongoing ENVISION Phase 3 trial and the design, timing and potential benefits thereof; the design and potential benefits of UGN-102 for the treatment of LG- IR-NMIBC, including as compared to alternative therapies; UroGen’s plans to file an NDA for UGN-102 and expected timing thereof; UroGen’s optimism regarding the clinical potential of UGN-102; the potential of UroGen’s proprietary RTGel technology platform to improve therapeutic profiles of existing drugs; and UroGen’s sustained release technology making local delivery potentially more effective as compared to other treatment option. These statements are subject to a number of risks, uncertainties and assumptions, including,

but not limited to: the timing and success of clinical trials and potential safety and other complications thereof, including the ENVISION Phase 3 trial; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with commercialization activities, including complications resulting from the COVID-19 pandemic; the labeling for any approved product; competition in our 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. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Form 10-Q filed with the SEC on November 10, 2022 and other filings that UroGen makes with the SEC from time to time (which are 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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