UroGen Announces Positive Interim Data from Phase 2b Study of UGN-102 in Patients with Low-Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer

April 3, 2020

- *Complete Response (CR) Rate of 65% at Three Months*
- *Of those with CR, 97% and 85% of Patients Remained Free of Disease at Six and Nine Months Follow-Up, Respectively*
- *Detailed Results Presentation to be Shared Virtually via American Urological Association (AUA) in mid-May*

PRINCETON, N.J.--(BUSINESS WIRE)--Apr. 3, 2020-- UroGen Pharma Ltd. (Nasdaq:URGN) announced positive interim data analysis of UGN-102 (mitomycin) for intravesical solution in patients with low-grade intermediate risk non-muscle invasive bladder cancer (LG IR-NMIBC). These data were featured in a late-breaking abstract published in the April Supplement to *The Journal of Urology*. The detailed results presentation will be available online via the American Urological Association (AUA) in mid-May 2020.

The Phase 2b OPTIMA II trial demonstrated a complete response (CR) rate at three months following onset of treatment of 65% (41/63 patients). In this subset of patients, 31/32 patients (97%) and 17/20 patients (85%) remained free of disease at six and nine months follow-up, respectively.

“The responses we have seen demonstrate that non-surgical primary chemoablation of low-grade intermediate risk non-muscle invasive bladder cancer using UGN-102 results in a considerable treatment response with encouraging durability,” said Dr. Mark Schoenberg, Chief Medical Officer at UroGen. “There are approximately 80,000 treatable patients annually in the US, but this remains a very challenging disease with high rates of recurrence associated with currently available therapies and a need for lifelong active surveillance and repetitive surgical intervention.”

The most commonly reported adverse events seen to date were reported as mild to moderate and include dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection.

About UGN-102

UGN-102 (mitomycin) for intravesical solution is an investigational drug formulation of mitomycin in Phase 2b development for the treatment of low-grade non-muscle invasive bladder cancer (LG NMIBC). Utilizing the RTGel™ Technology Platform, UroGen’s proprietary 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 standard intravesical catheters. The Company completed enrollment in the Phase 2b OPTIMA II trial of UGN-102 for the treatment of LG NMIBC in September 2019 and intends to advance the program to a pivotal study to further investigate UGN-102 in the treatment of this condition.

About UroGen Pharma Ltd.

UroGen is a biopharmaceutical company dedicated to building novel solutions that treat specialty cancers and urologic diseases 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 lead investigational candidates, UGN-101 (mitomycin) for pyelocalyceal solution, and UGN-102 (mitomycin) for intravesical solution, are designed to ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer and low-grade non-muscle invasive bladder cancer, respectively. UroGen is headquartered in Princeton, NJ with operations in New York, NY and 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: the potential for UGN-101 to be approved as a treatment option for LG UTUC; the potential of UroGen’s proprietary RTGel™ technology platform to improve therapeutic profiles of existing drugs; the opportunity and potential of UGN-102 for LG NMIBC; and plans to advance UGN-102 into a pivotal study. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the timing and success of clinical trials, including the OLYMPUS Phase 3 trial and the planned pivotal trial for UGN-102 and potential safety and other complications thereof; the ability to obtain regulatory approval within the timeframe expected, or at all; the ability to maintain regulatory approval; complications associated with achieving commercial readiness for the launch of a new product; the labeling for any approved product; 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 personnel; and any negative effects on UroGen’s business and product development plans caused by or associated with COVID-19. 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-K filed with the SEC on March 2, 2019, 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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