Relmada Therapeutics to Host KOL Event on Phase 2 NDV-01 Data

Description

April 28th AUA data presentation to highlight study in patients with high-grade non-muscle invasive bladder cancer (HG-NMIBC)

Virtual event to be held on April 28, 2025 at 4:30 PM ET

CORAL GABLES, Fla., April 24, 2025 (GLOBE NEWSWIRE) — Relmada Therapeutics, Inc. (Nasdaq: RLMD, “Relmada”, “the Company”), a clinical-stage biotechnology company, today announced it will host a virtual key opinion leader (KOL) event on Monday, April 28, 2025 at 4:30 PM ET. To register, please click here.

The event will feature Boris Chertin, MD (Department of Urology, Shaare Zedek Medical Center) and Yair Lotan, MD (UT Southwestern Medical Center), who will join Relmada’s management to discuss topline efficacy and safety data from the Phase 2 study evaluating NDV-01 for the treatment of high-grade non-muscle invasive bladder cancer (HG-NMIBC). The data will be presented at the American Urological Association meeting (AUA), on April 28, 2025 in Las Vegas, Nevada.

NDV-01 is a novel, investigational, sustained-release gemcitabine/docetaxel formulation, designed as a ready-for-use intravesical therapy for the treatment of NMIBC. The U.S. prevalence of NMIBC is approximately 600,000 patients, with an estimated 62,000 patients diagnosed annually.

A live question and answer session will follow the formal presentation.

About Boris Chertin, MD
Boris Chertin, MD is Chairman of the Department of Urology & Pediatric Urology at the Shaare Zedek Medical Center. Professor Chertin is also affiliated with the Faculty of the Medical Science, Hebrew University, Jerusalem, Israel and former Deputy, General Manager, Shaare Zedek Medical Center. He is an adult and pediatric urologist, and focuses on children with disorders in their urogenital systems from birth to adolescence. He is a Clinical Professor in Surgery and Urology at Hebrew University, Jerusalem. Professor Chertin has served on multiple national and international committees advancing urology.

About Yair Lotan, MD
Yair Lotan, MD, is a Professor of Urology, Chief of Urologic Oncology, and holder of the Jane and John Justin Distinguished Chair in Urology, in Honor of Claus G. Roehrborn, M.D. at UT Southwestern Medical Center. He is also the Medical Director of the Urology Clinic at UT Southwestern and Parkland Health and Hospital System. He was class valedictorian in high school and graduated with high honors from the University of Texas at Austin and Baylor College of Medicine in Houston. He trained in general surgery and urology at UT Southwestern and joined the faculty in 2003. A board-certified urologist, Dr. Lotan treats patients with bladder, prostate, kidney, ureteral, and testicular cancer. He also handles general urologic conditions, such as kidney stones and vasectomies. He is known nationally for his research on urine markers and molecular markers, which will help determine which patients are at higher risk for

recurrent cancer. He is also involved in health economics research, which evaluates the cost-effectiveness of surgery and cancer prevention. Dr. Lotan is the co-chair of the Harold C. Simmons Comprehensive Cancer Center disease-oriented team for urologic cancers. He is also a member of UT Southwestern's Clinical Research Planning Group and the Tissue Bank Steering Committee and Cancer Committee. He is a frequent guest speaker at medical conferences around the world and belongs to numerous professional organizations, including the American Urological Association, the Society of Urologic Oncology, and the Bladder Cancer Advocacy Network. He has published hundreds of research articles and several book chapters on urologic care and procedures, and he serves as editorial reviewer for medical periodicals such as the Journal of Urology, European Urology, Cancer, Urologic Oncology, and the British Journal of Urology International. Dr. Lotan was included in D Magazine's Best Doctors list for 2018, 2021, and 2022.

About NDV-01

NDV-01 is an investigational, innovative sustained-release formulation of two complementary, well-established, chemotherapy agents, gemcitabine and docetaxel (gem/doce). It is designed for intravesical dosing and intended to be an in-office ready-to-use therapy that is administered rapidly and requires no anesthesia or new or dedicated equipment to employ. NDV-01 forms a spherical soft matrix within the bladder that sequesters drug and releases it as the matrix gradually dissolves.

NDV-01's formulation is specifically designed to maximize local drug concentration and prolong exposure to gem/doce, while minimizing systemic toxicity. Unlike conventional intravesical instillations, NDV-01 is designed to avoid peaks and troughs in drug concentration, ensuring a gradual and sustained release of gem/doce over a 10-day period. This approach may potentially enhance overall efficacy, reduce side effects, reduce the frequency of dosing and improve patient compliance and outcomes. NDV-01 has the potential to be a first line (1L) therapy for HG-NMIBC, with further potential for use in patients who have failed other therapies, including BCG immunotherapy, and expansion into other NMIBC subtypes, including intermediate-grade disease.

NDV-01 is protected by several patents that extend out to 2038.

About NMIBC

More than 90% of the approximately 83,000 new U.S. cases of urothelial cancer are estimated to be bladder cancer. For the overall bladder cancer population, 5-year survival ranges from 70 to 96% of patients, moving to 6% for patients with advanced disease. Roughly 75% of bladder cancer cases are classified as non-muscle invasive (NMIBC) and approximately 50% of cases are classified as high-grade disease, considered to have increased risk of progression and recurrence. Sources indicate that NMIBC has a 50-75% recurrence rate (over seven years) and that the U.S. prevalence of NMIBC is approximately 600,000 patients.

The U.S. NMIBC market is estimated to be a multi-billion opportunity. Global numbers are higher, in line with projections for significant growth due to the increasing incidence of bladder cancer and the demand for effective, minimally invasive potential therapies like NDV-01. Approved treatment options remain limited (mainly the immunotherapy, BCG, which has been supply constrained for some time), with high recurrence rates leading to frequent re-treatment and progression. Other emerging programs include immunotherapy combinations, single agent chemotherapy formulations and targeted therapies. NDV-01 stands out based on the large body of published data that support the efficacy of treatment with

gemcitabine and docetaxel, its ease of administration and potential for durability of action. Expansion beyond first-line treatment into use as a salvage treatment or in other subgroups of NMIBC, including naïve patients, could further increase the opportunity for NDV-01.

About Relmada Therapeutics, Inc.
Relmada Therapeutics is a clinical-stage biotechnology company committed to advancing innovative breakthrough therapies that have the potential to bring meaningful clinical benefits to targeted patient populations.

Lead investigational program, NDV-01, for High-Grade Non-Muscle Invasive Bladder Cancer, is being evaluated in a Phase 2 study. In addition, preparations are underway to advance sepranolone, a Phase 2b-ready investigational program for compulsion-related disorders including Tourette's Syndrome and Prader-Willi syndrome, into further studies.

For more information, visit www.relmada.com.

Forward-Looking Statements:
The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by us or on our behalf. This press release contains statements which constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Any statement that is not historical in nature is a forward-looking statement and may be identified by the use of words and phrases such as "if", "may", "expects", "anticipates", "believes", "will", "will likely result", "will continue", "plans to", "potential", "promising", and similar expressions. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including potential for Phase 2 NDV-01 data to be presented at an upcoming medical conference, potential for Phase 2 NDV-01 data to deliver positive results supporting further development, potential for clinical trials to deliver statistically and/or clinically significant evidence of efficacy and/or safety, failure of top-line results to accurately reflect the complete results of the trial, failure of planned or ongoing preclinical and clinical studies to demonstrate expected results, potential failure to secure FDA agreement on the regulatory path for sepranolone, and NDV-01, or that future sepranolone, or NDV-01 clinical results will be acceptable to the FDA, failure to secure adequate sepranolone, or NDV-01 drug supply and the other risk factors described under the heading "Risk Factors" set forth in the Company's reports filed with the SEC from time to time. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Relmada undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Readers are cautioned that it is not possible to predict or identify all the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be a complete list.

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