April 14, 2025

Relmada Therapeutics To Present NDV-01 Data at AUA2025

Data to be presented on Monday, April 28, 2025

CORAL GABLES, Fla., April 14, 2025 (GLOBE NEWSWIRE) -- Relmada Therapeutics, Inc. (Nasdaq: RLMD, “Relmada”, “the Company”), a clinical-stage biotechnology company, today announced the presentation of an abstract at the American Urology Association (AUA2025), taking place from April 26-29th in Las Vegas.

Abstract Overview

Abstract Title:	Prospective Open Label Study to Evaluate the Safety and Efficacy of Safety and Efficacy of intravesical sustained release Gemcitabine Docetaxel combination (NDV-01) in High Risk NMIBC: P2 on Apr 25
Session:	P2 (Paradigm-Shifting)
Presentation Date:	April 28, 2025
Presentation Time	10:04 AM PT

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 go 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 450,000 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 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.

Investor Contact:
Brian Ritchie
LifeSci Advisors
britchie@lifesciadvisors.com

Media Inquiries:
Corporate Communications
media@relmada.com

Source: Relmada Therapeutics