

Relmada Therapeutics Announces Presentation of NDV-01 Phase 2 Data at the Society for Urologic Oncology

Description

Poster highlights 6-month follow-up data from the ongoing Phase 2 trial of NDV-01 in non-muscle invasive bladder cancer (NMIBC), with favorable overall safety

Relmada plans to advance NDV-01, a sustained release intravesical formulation of gemcitabine/docetaxel (Gem/Doce), into Phase 3 studies in two indications in H1 2026

Company is focused on high-risk NMIBC and intermediate-risk NMIBC, representing about 80% of new NMIBC cases every year, or about 54,000 people in the United States

CORAL GABLES, Fla., Dec. 03, 2025 (GLOBE NEWSWIRE) — [Relmada Therapeutics, Inc.](#) (Nasdaq: RLMD, “Relmada” or the “Company”), a clinical-stage biotechnology company advancing innovative therapies for oncology and central nervous system indications, today announced that the previously disclosed 6-month follow-up data from the ongoing Phase 2 study of NDV-01, a sustained release, intravesical formulation of gemcitabine and docetaxel (Gem/Doce), in development for non-muscle invasive bladder cancer (NMIBC) will be presented in a poster at the Society of Urologic Oncology 26th Annual Meeting (SUO 2025). The poster (#143) will be presented by Yair Lotan, MD, Chairman of Relmada’s Clinical Advisory Board, on Thursday, December 4th at 2:30 PM MT in Phoenix, AZ.

Raj S. Pruthi, MD, Chief Medical Officer-Oncology of Relmada Therapeutics, noted, “We believe NDV-01 has the opportunity to transform the treatment of NMIBC by providing patients and physicians with a potential bladder-sparing, in-office, ready-to-use, safe, effective and durable, best-in-class therapy. We are on track to initiate the Phase 3 program in H1 2026, building on the encouraging, recently announced 9-month data, showing a 92% complete response (CR) rate at any time point, and encouraging recent FDA discussions, which provide us with a well-defined registrational strategy in two distinct indications in NMIBC with limited treatment options.”

The Society of Urologic Oncology 26th Annual Meeting Information:

- Title: [Prospective Open-Label Study to Evaluate the Safety and Efficacy of Intravesical Sustained-Release Gemcitabine Docetaxel combination \(NDV-01\) in High-Risk NMIBC: Update with 6-month Complete Response Data](#)
- Poster Number: #143
- Date and Time: Thursday, December 4th at 2:30 PM MT

A copy of the poster will be available on the Events section of the Relmada website after the session. To review the an overview of the 9-month data and FDA discussions, click [here](#).

About NDV-01

NDV-01 is a sustained-release, intravesical formulation of gemcitabine and docetaxel (Gem/Doce), in development for the treatment of non-muscle invasive bladder cancer. It is designed to enable Gem/Doce bladder retention and gradual drug release over 10 days. The formulation creates a soft matrix that enhances local exposure while minimizing systemic toxicity. The NDV-01 formulation is a ready to use, convenient to administer in-office in less than 10 minutes, and does not require anesthesia or specialized equipment. It is protected by patents through 2038.

About the Phase 2 Study

The Phase 2 study (NCT06663137) is an open-label, single-arm, single-center study evaluating the safety and efficacy of NDV-01 in patients with HG-NMIBC. Patients are treated with NDV-01 in a biweekly induction phase, follow by monthly maintenance for up to one year, with regular assessments via cystoscopy, cytology, and biopsy, as indicated. The primary efficacy endpoints are safety and complete response rate (CRR) at 12 months, and secondary efficacy endpoints are duration of response (DOR) and event free survival (EFS).

About NMIBC

NMIBC represents 75-80% of all bladder cancer cases and is associated with high recurrence (50–80% over 5 years). With over 744,000 prevalent cases in the U.S. and limited treatment options, the market opportunity is significant. NDV-01 has the potential to serve as a frontline or salvage therapy and could be applicable across multiple NMIBC subtypes.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage biotechnology company focused on developing transformative therapies for oncology and central nervous system conditions. Its lead candidates, NDV-01 and sepranolone, are advancing through mid-stage clinical development with the potential to address significant unmet needs.

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 Relmada’s product candidates to progress, including the potential for Phase 2 NDV-01 data to continue 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 continue to secure FDA agreement on the regulatory path for NDV-01 and/or sepranolone, or that future NDV-01 and/or sepranolone clinical results will be acceptable to the FDA, failure to secure adequate NDV-01 and/or sepranolone drug supply, the Company's cash runway and sufficiency of the Company's cash resources and uncertainties inherent in estimating the Company's cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials, 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 are not a complete list.

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