May 5, 2026

Relmada Therapeutics to Present NDV-01 Abstracts at AUA2026

- *12-Month Phase 2 data in High-Risk NMIBC to be presented Friday, May 15, 2026*
- *Phase 3 overview to be presented at Trials-in-Progress session on Sunday, May 17, 2026*
- *The Phase 3 "RESCUE" registrational program remains on track to be initiated mid-2026*

CORAL GABLES, Fla., May 05, 2026 (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 disorders, today announced the presentation of two abstracts related to NDV-01 at the American Urology Association (AUA2026), taking place from May 15-18th in Washington D.C.**

Abstract Overview*

Abstract #1: Poster presentation: IP02-03: 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 9-month Complete Response Data

- Session: IP02: Bladder Cancer: Non-Invasive I
- Location: Room 146A, Walter E. Washington Convention Center
- Presentation Date: Friday, May 15, 2026
- Presentation Time: 7:00 AM to 9:00 AM ET

Abstract #2: Oral presentation: Trial in Progress: REL-NDV01-301 (BOOST) - A Phase 3, Randomized Study of Adjuvant Intravesical Sustained-Release Gemcitabine-Docetaxel (NDV-01) Versus Surveillance for the Treatment of Intermediate-Risk Non-Muscle Invasive Bladder Cancer.

- Session: Clinical Trials in Progress: Bladder Cancer
- Location: Hall B, The Square, Learning Lab, Walter E. Washington Convention Center
- Presentation Date: Sunday, May 17, 2026
- Presentation Time: 9:56 AM to 10:04 AM ET

*Exact conference presentation times and locations may be subject to change.

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 ready to use, convenient to administer in-office in less than 5 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 high-grade non-muscle invasive bladder cancer (HG-NMIBC). Patients are treated with NDV-01 in a biweekly induction phase, followed 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. High-grade BCG-unresponsive disease represents one of the most difficult-to-treat NMIBC subtypes, with limited bladder-sparing options. Intermediate-risk NMIBC in the adjuvant setting has no currently approved therapies. 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 interim or 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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Source: Relmada Therapeutics