March 9, 2026

Relmada Therapeutics Reports 12-Month Phase 2 Interim Data for NDV-01 in Non-Muscle Invasive Bladder Cancer

- *Durable 76% complete response (CR) rate at 12 months with 95% CR rate at any time in high-risk NMIBC*
- *BCG-unresponsive patients achieved an 80% CR rate at 12 months and 94% CR rate at any time*
- *Tolerability profile remains favorable – no ≥ Grade 3 treatment-related adverse events and no treatment-related discontinuations*
- *Data reinforces advancement of NDV-01 into Phase 3 RESCUE registrational program in second line (2L) BCG-unresponsive and adjuvant intermediate-risk NMIBC in mid-2026*

CORAL GABLES, Fla., March 09, 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 **12-month interim data from its ongoing Phase 2 trial evaluating NDV-01 in patients with high-risk non-muscle invasive bladder cancer (NMIBC).**

The Phase 2 trial of NDV-01 demonstrated a **12-month complete response (CR) rate of 76% with a favorable safety profile**. Notably, a **12-month CR rate of 80% was achieved in the BCG-unresponsive population**, one of the most difficult-to-treat segments of NMIBC. Taken together, these findings support the **potential best-in-class profile of NDV-01** and support advancement into **the Phase 3 RESCUE registrational program evaluating NDV-01 in both 2L BCG-unresponsive and adjuvant intermediate-risk NMIBC.**

"These 12-month data show the potential durability of NDV-01's clinical response profile while continuing to demonstrate a clean safety profile," said **Raj S. Pruthi, MD, Chief Medical Officer-Oncology of Relmada Therapeutics**. "Importantly, we continue to observe strong responses in patients with BCG-unresponsive disease, with no progression to muscle-invasive disease and no patients requiring radical cystectomy. We believe these interim results provide meaningful clinical validation of the program and support advancing NDV-01 into the registrational Phase 3 RESCUE program with two separate registrational pathways: 2L BCG-unresponsive and adjuvant intermediate-risk, which we expect to initiate in mid-2026."

"I am highly encouraged by NDV-01's high response rates, 12-month durability and favorable tolerability profile. Building on the clinical community's familiarity with conventional Gem/Doce, these Phase 2 results provide robust validation of NDV-01's novel sustained release formulation. In addition, NDV-01's less than 5-minute administration simplifies dosing for clinical staff, supporting broad adoption in community urology practices where

~80% of NMIBC patients are treated – and potentially offering a significantly more streamlined user experience than currently approved therapies," said **Max Kates, MD, Director of Urologic Oncology at Johns Hopkins and Relmada Clinical Advisor.**

Highlights of the 12-month follow-up data from the Ongoing Phase 2 study of NDV-01:

Clinical Results (Response Data)	
Complete Response	
Anytime	95% (36/38)
3 month	87% (33/38)
6 month	86% (25/29)
9 month	85% (22/26)
12 month	76% (19/25)
12-month KM analysis	83%
N=48 patients dosed in overall population; KM: Kaplan-Meier analysis	

Efficacy in BCG-Unresponsive Subpopulation:**

Clinical Results (Response Data)	
Complete Response	
Anytime	94% (16/17)
3 month	82% (14/17)
6 month	86% (12/14)
9 month	91% (10/11)
12 month	80% (8/10)
12-month KM analysis	84%
N=20 patients dosed in BCG-UR subpopulation; ** BCG-UR defined by FDA definition; BCG-UR: Bacillus Calmette-Guérin (BCG) – Unresponsive; KM: Kaplan-Meier analysis	

- No patient had progression to muscle-invasive disease
- No patient underwent a radical cystectomy
- No patients had a ≥ Grade 3 treatment related adverse event (TRAE)
- No patients discontinued treatment due to AEs
- Of the 48 patients who received ≥ 1 dose, 30 (63%) experienced a treatment-related adverse event (AE).
- Among treatment-related AEs,
    - 54% were transient uncomfortable urination (dysuria, <24 hours, Grade 1)
    - 8% had an asymptomatic positive urine culture
    - 8% had hematuria

Phase 3 RESCUE Registrational Pathways:

Registrational Pathway 1 – An open label randomized controlled trial in intermediate-risk NMIBC of adjuvant therapy following TURBT (NDV-01 vs. observation). There are no approved treatments for adjuvant intermediate risk NMIBC, which we estimate affects ~75,000 patients/year in the US.

- **Primary endpoint:** Disease Free Survival (DFS)
- **Key secondary endpoints:** High-grade recurrence free survival (HG-RFS), progression free survival (PFS), quality of life (QOL) metrics

Registration Pathway 2 – A single-arm trial in second line (2L) BCG-unresponsive NMIBC

with *carcinoma in situ (CIS)* patients who are currently refractory to approved or developmental therapies. Patients with BCG-unresponsive NMIBC with *CIS* who fail first line (1L) therapies, which we estimate to affect ~5,000 patients/year in the US, have few, if any, effective treatment alternatives to radical cystectomy.

- **Primary endpoint:** Complete response (CR) rate at any time
- **Key secondary endpoint:** Duration of response (DOR), progression free survival (PFS), recurrence free survival (RFS) amongst responders

Expected Upcoming NDV-01 Milestones:

- NDV-01 United States IND clearance – Mid-2026
- Phase 3 RESCUE Program Initiation – Mid-2026
- Initial 3-month results from Phase 3 2L BCG-unresponsive study expected by YE 2026

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 approximately 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 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 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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