November 4, 2025

Relmada Announces FDA Feedback Supporting 2 Separate Acceptable Registrational Study Paths for NDV-01 in Non-muscle Invasive Bladder Cancer

Announces NDV-01 9-Month Follow-up Safety and Efficacy Data in NMIBC

FDA feedback supports 2 potential registrational trials – 1) a registrational trial in 2nd line refractory BCG-unresponsive NMIBC, and 2) a randomized controlled trial in intermediate-risk NMIBC.

FDA Feedback also confirms no additional non-clinical studies are required.

9-month follow-up for NDV-01 showed a 92% overall response rate at any time in non-muscle invasive bladder cancer, with good overall safety

CORAL GABLES, Fla., Nov. 04, 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 the receipt of written minutes from a Type B pre-IND meeting with the U.S. Food and Drug Administration (FDA) regarding the planned Phase 3 program for NDV-01 in non-muscle invasive bladder cancer (NMIBC) patients. The Company will be requesting follow-up meetings with FDA to discuss each development path. Relmada secured FDA alignment on certain key elements of the planned Phase 3 pivotal program for NDV-01, expected to begin in H1 2026 and incorporating two independent studies for approval in two separate indications:

- High-grade, 2nd line BCG-unresponsive NMIBC patients
- Intermediate risk NMIBC in the adjuvant setting

Key Outcomes from the FDA Type B pre-IND meeting (specific study design details to be further discussed with the agency):

- **In high-grade, 2nd line BCG-unresponsive setting, the FDA stated that a single arm trial might be acceptable in a more refractory patient population.**
- **In the intermediate risk NMIBC setting, the FDA agreed that a proposal to randomize patients post-TURBT to adjuvant NDV-01 vs observation, evaluating a time-to-event endpoint, is generally acceptable**.
- **Further non-clinical studies are not required**. FDA indicated that no further non-clinical studies are required to support a 505(b)(2) New Drug Application (NDA).

"The positive outcome of our Type B meeting and alignment with the FDA on the Phase 3

pivotal program mark a key milestone for Relmada and NDV-01," said **Raj Pruthi, MD, Chief Medical Officer – Urology**, Relmada Therapeutics. "We believe the FDA's guidance provides a path to advance NDV-01 for patients with NMIBC who currently have limited options. We believe a single-arm registrational study in high-grade, refractory BCG-unresponsive patients offers a rapid route to potential approval, while alignment on a separate second pivotal study in intermediate-risk NMIBC could enable an additional indication and broader clinical adoption."

Sergio Traversa, Chief Executive Officer of Relmada Therapeutics, stated: "We added NDV-01 to our portfolio based on its strong potential to transform the treatment of NMIBC. The outcome of our Type B meeting with the FDA further reinforces our confidence in the path forward and in NDV-01's potential to become a best-in-class, durable, ready and easy-to-use, in-office, bladder-sparing therapy. We look forward to initiating the Phase 3 programs in the first half of 2026."

Also, Relmada announced 9-month follow-up data from the Phase 2 study of NDV-01 in non-muscle invasive bladder cancer.

Highlights of the 9-month follow-up data and updated 3-month and 6-month data from the Phase 2 study of NDV-01:

Clinical Results (Response Data)	
Complete Response	% (n/N)
Anytime	92% (23/25)
3 months	84% (21/25)
6 months	87% (20/23)*
9 months	85% (17/20)*

*Includes patients with CR after re-induction. 60% CR rate after re-induction.

- Two subjects have reached 12-month assessment, and both have a CR
- No patient had progression to muscle invasive disease
- No patient underwent a radical cystectomy
- No new safety signals in terms of type, number, or degree of AEs -- with no patients having a >= Grade 3 TRAE and no patients discontinued treatment due to AEs
- 36 enrolled patients (receiving >= 1 dose), of which 22 (61%) experienced a treatment-related AE. Among treatment-related AEs, 62% were transient uncomfortable urination (dysuria), 9% were asymptomatic positive urine culture and 7% were hematuria.

Efficacy in BCG-Unresponsive Subpopulation:**

Clinical Results (Response Data)	
Complete Response	% (n/N)
Anytime	91% (10/11)
3 months	82% (9/11)
6 months	78% (7/9)
9 months	88% (7/8)

- n = 18 patients dosed in BCG-UR subpopulation
- BCG-UR defined by FDA definition**

BCG-UR, Bacillus Calmette-Guérin (BCG) – Unresponsive

**https://www.fda.gov/media/101468/download.

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 tumor exposure. NDV-01 is ready to use, convenient to administer in-office in less than 10 minutes, and does not require preparation, anesthesia or specialized equipment.

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, 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 sepranolone, or that future NDV-01, or sepranolone, clinical results will be acceptable to the FDA, failure to secure adequate NDV-01, or sepranolone, 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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