Relmada Therapeutics Provides Regulatory Update Confirming FDA Alignment on Registrational Studies Design for NDV-01 for Two Separate Indications

Description

FDA written feedback supports:

– a single-arm, open-label registrational trial in 2nd-line refractory high-grade NMIBC with CIS

– a randomized vs observation single trial in intermediate-risk NMIBC in the adjuvant setting

Phase 3 program expected to initiate in 1H 2026

CORAL GABLES, Fla., Jan. 12, 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 that it has received written feedback from the U.S. Food and Drug Administration (FDA) regarding the registrational development pathway for NDV-01 in **2nd-line refractory, high-grade BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma *in situ* (CIS)** — one of the highest-risk and most treatment-resistant NMIBC populations — and **in intermediate risk NMIBC in the adjuvant setting, where there are currently no approved therapies.**

In its written response to Relmada's Type B pre-IND submission, **the FDA indicated that a single-arm, open-label clinical trial in this high-grade, BCG-unresponsive with CIS population is an appropriate registrational approach for NDV-01.** This feedback provides a clear and efficient development path toward a potential NDA submission for NDV-01 as a bladder-sparing therapeutic option in a patient population with significant unmet need.

The FDA also provided separate, supportive written feedback on the Company's planned **single registrational study in intermediate-risk NMIBC in the adjuvant setting,** which is expected to follow an open-label, randomized-to-observation design.

Relmada continues to anticipate initiating both registrational trials in the first half of 2026.

"We are very pleased with the FDA's alignment on the registrational design for NDV-01 in high-grade BCG-unresponsive NMIBC," said **Raj S. Pruthi, MD, Chief Medical Officer – Oncology** at Relmada Therapeutics. "A single-arm pivotal study in this setting represents a meaningful opportunity to advance an in-office, bladder-sparing therapy for patients who have few if any effective alternatives. This study represents the fastest path to approval for NDV-01."

Dr. Pruthi continued, "We are also encouraged by the FDA's feedback on our intermediate-risk registration plans, where we believe NDV-01 could potentially provide meaningful clinical benefit to patients where no approved treatments currently exist."

About the Planned High-Grade Registrational Study

The planned pivotal Phase 3 study in 2nd-line, refractory, high-grade BCG-unresponsive NMIBC with carcinoma *in situ* (CIS) will be an open-label, single-arm trial evaluating:

- **Primary endpoint:** Complete response (CR) rate at any time
- **Key secondary endpoint:** Duration of response (DOR)
- **Assessments:** Cystoscopy, cytology, and biopsy per protocol

The design reflects FDA's written guidance on the study population, endpoint selection, and evaluation methodology and is consistent with prior FDA precedents for single-arm registrational trials in NMIBC.

About the Planned Intermediate-Risk Registrational Study

The planned pivotal Phase 3 study in intermediate-risk NMIBC in the adjuvant setting will be an open label randomized-to-observation study:

- **Primary endpoint:** Disease Free Survival (DFS)
- **Key secondary endpoint:** Duration of response (DOR)
- **Assessments:** Cystoscopy, cytology, and biopsy per protocol

The design reflects FDA's written guidance on the study population, endpoint selection, and evaluation methodology.

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 ten 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 five minutes, and does not require anesthesia or specialized equipment. It is protected by patents through 2038.

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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