# Relmada Therapeutics Appoints Distinguished Urologic Oncologist, Max Kates, MD, to the Clinical Advisory Board to Support Development of NDV-01

## Description

*Dr. Kates' experience as chair of the landmark Phase 3 BRIDGE bladder cancer trial and dedication to patient care will be invaluable to the NDV-01 Phase 3 program*

*Phase 3 program for NDV-01 expected to begin in H1 2026*

CORAL GABLES, Fla., Oct. 07, 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 appointment of Max Kates, MD, Associate Professor of Urology and Oncology at Johns Hopkins University School of Medicine, to Relmada's Clinical Advisory Board (CAB) to support the development of NDV-01 for the potential treatment of non-muscle invasive bladder cancer (NMIBC). Relmada intends to initiate the Phase 3 program for NDV-01 in H1 2026.

"With preparations actively underway for the Phase 3 NDV-01 clinical program in NMIBC, we are very pleased to welcome Dr. Kates to the Relmada Clinical Advisory Board. We believe that Max's experience chairing the landmark Phase 3 BRIDGE trial and leading several other practice-changing studies gives him a unique clinical perspective that will be invaluable to the design and conduct of the Phase 3 program," said **Raj Pruthi, MD, Chief Medical Officer-Urology**, Relmada. "In addition, Max's first-hand knowledge of the operational complexities inherent to a high-volume urologic oncology practice will help us to strengthen the Phase 3 program for NDV-01 and ensure its real-world applicability."

"As the chair of the international Phase 3 Bridge Study, I have gained a deep appreciation for the clinical community's optimism for the intravesicular delivery of gemcitabine and docetaxel as a potential bladder sparing treatment for NMIBC," said **Dr. Kates**. "The initial safety and efficacy data for NDV-01, presented at the American Urologic Association in April, 2025, and updated in August, underscore the significant benefit that a sustained release formulation of "Gem/Doce" could offer urologic oncology practices and bladder cancer patients. I believe NDV-01 has the potential to transform the treatment of NMIBC and I am pleased to join the Relmada Clinical Advisory Board and eager to contribute my expertise to the pivotal program."

**About Max Kates, MD**
Dr. Kates is a nationally recognized clinician-scientist in bladder cancer with one of the largest surgical bladder cancer practices in the U.S., integrating clinical care with translational research.

Dr. Kates serves as chair of the Phase 3 EA8212 BRIDGE Trial (NCT05538663) trial, comparing Gemcitabine/Docetaxel to BCG (Bacillus Calmette-Guérin) in non–muscle invasive bladder cancer (over 900 patients enrolled across >65 centers). He has also been the Principal Investigator on numerous studies evaluating new potential treatments for NMIBC. Dr. Kates has pioneered improvements in surgical innovation for robotic intracorporeal cystectomy and neobladder as well as novel techniques and early

recovery programs for TURBT translational research, has advanced understanding of immune resistance in BCG-unresponsive disease, pioneered novel intravesical therapies, and explored antibody–drug conjugates and immunotherapy for bladder preservation.

Throughout his career, Dr. Kates has published more than 150 peer-reviewed manuscripts in leading journals such as *Clinical Cancer Research*, *Cancer Immunology Research, Journal of Urology*, and *European Urology*. Dr. Kates also serves as a reviewer for prominent journals including the *New England Journal of Medicine*, and the *Journal of Clinical Oncology*.

Dr. Kates is the R. Christian B. Evensen Professor of Urology and Director of the Division of Urologic Oncology at Johns Hopkins Hospital, and Associate Professor, Urology and Oncology and Co-Director of the Greenberg Bladder Cancer Institute. He received his medical degree from Mount Sinai School of Medicine in New York. He trained in general surgery and urologic surgery at John Hopkins Hospital in Baltimore, Maryland and completed a Clinical Research Fellowship at Columbia University College of Physicians and Surgeons in New York. Dr. Kates graduated with High Distinction with a B.A. from Wesleyan University.

**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. NDV-01 is 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 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-related 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 the 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 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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