Relmada Therapeutics Appoints Renowned Urologic Oncologist, Yair Lotan, MD, to Chair the Clinical Advisory Board and Support Development of NDV-01

Description

Dr. Lotan's distinguished expertise in bladder cancer care and clinical development brings further scientific acumen to Relmada's NDV-01 program

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

CORAL GABLES, Fla., July 15, 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 Yair Lotan, MD, a distinguished urologic oncologist, as Chair of Relmada's Clinical Advisory Board (CAB). Dr. Lotan's deep expertise in bladder cancer care and clinical research will be invaluable as Relmada prepares to initiate a Phase 3 trial for NDV-01 in H1 2026, building on positive Phase 2 data, presented at the American Urology Association 2025 Annual Meeting (AUA 2025) on April 28, 2025.

Dr. Lotan brings more than two decades of experience in bladder cancer care, clinical development and academic medicine. As a nationally recognized expert in molecular biomarkers, with involvement in the establishment of practice guidelines for the management of bladder cancers and health economics research, Dr. Lotan is well suited to Chair Relmada's Clinical Advisory Board and to help shape the clinical development strategy for NDV-01.

"We believe that Yair's first-hand understanding of the current treatment challenges in bladder cancer, combined with his deep clinical development expertise, will help to strengthen and enrich the clinical development program for NDV-01," said **Sergio Traversa, Chief Executive Officer**, Relmada. "As we prepare to advance NDV-01 to Phase 3 studies, we are confident that Yair's leadership of our Clinical Advisory Board and his prominent role in the bladder cancer community will help to position the program for success."

Raj Pruthi, MD, Chief Medical Officer-Urology, Relmada noted, "In my experience, a Clinical Advisory Board can play a vital role in the progression of an innovative product candidate, providing scientific insights and strategic advice. Relmada's goal is to bring NDV-01 to patients with non-muscle invasive bladder cancer (NMIBC) as soon as possible. We are very pleased to have Yair on board to Chair Relmada's Clinical Advisory Board. His influential thought-leadership will help Relmada to optimize our product development plan for NDV-01."

"In my view, impressive initial Phase 2 data presented at AUA 2025 solidly support NDV-01's unique potential to become a class-leading, bladder-sparing therapy for the treatment of NMIBC," commented **Dr. Lotan, CAB Chair,** Relmada. "While the combination of gemcitabine/docetaxel (Gem/Doce) has been embraced by the medical community, it is difficult to formulate the combination outside of a hospital setting. NDV-01's simple, ready-to-use sustained release formulation could enable wider patient adoption and transform the care of NMIBC. I am excited to Chair the Clinical Advisory Board at this pivotal time for

Relmada."

About Yair Lotan, MD

Yair Lotan, MD, is a urologic oncologist with over 20 years of experience caring for bladder cancer patients.

Dr. Lotan graduated with high honors from the University of Texas at Austin and with honors from Baylor College of Medicine in Houston. He trained in general surgery and urology at UT Southwestern Medical Center in Dallas. Dr. Lotan heads a clinical research office and is involved in many clinical trials related to bladder cancer.

Dr. Lotan is known nationally for his research on urine markers and molecular markers, which will help determine which patients are at higher risk for recurrent cancer. He is also involved in health economics research, which evaluates the cost-effectiveness of surgery and cancer prevention. Dr. Lotan has participated in multiple collaborative studies involving early detection of bladder cancer. He is also a co-investigator on several NIH funded trials evaluating urine-based tumor markers. Dr. Lotan is the primary investigator on several investigator-initiated studies evaluating the role of urine and tissue markers in the management of bladder cancer. He is a member of panels that establish guidelines for the evaluation of hematuria and management of muscle invasive bladder cancer. Dr. Lotan has published over 650 peer reviewed papers and multiple reviews and book chapters.

Dr. Lotan is a frequent guest speaker at medical conferences around the world and belongs to numerous professional organizations, including the American Urological Association, the Society of Urologic Oncology, and the Bladder Cancer Advocacy Network. He also serves as editorial reviewer for medical periodicals such as the *Journal of Urology*, *European Urology*, *Cancer*, *Urologic Oncology*, and the *British Journal of Urology International*.

Dr. Lotan has been included in D Magazine's Best Doctors list multiple times over the last decade.

About NDV-01

NDV-01 is a sustained-release, intravesical formulation of gemcitabine and docetaxel (Gem/Doce), in development for the treatment of 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 designed to be administered 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% of all bladder cancer cases and is associated with high recurrence (50 –75% over 7 years). With over 600,000 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 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-10, 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.

Investor Contact:
Brian Ritchie
LifeSci Advisors
britchie@lifesciadvisors.com

Media Inquiries:
Corporate Communications
media@relmada.com

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