June 17, 2025

Relmada Therapeutics Appoints Urology Expert Raj S. Pruthi, MD as CMO-Urology

Dr. Pruthi brings vast clinical development experience advancing novel therapies for NMIBC

to Relmada and the NDV-01 program

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

CORAL GABLES, Fla., June 17, 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 Raj S. Pruthi, MD as Chief Medical Officer-Urology (CMO). Dr. Pruthi's expertise will be instrumental in the development of Relmada's lead program, NDV-01, for non-muscle invasive bladder cancer (NMIBC). The Company presented positive initial Phase 2 data at the American Urology Association 2025 Annual Meeting (AUA 2025) on April 28, 2025.

Dr. Pruthi is a highly regarded physician-scientist with over 25 years of experience in industry and academic medicine, specializing in urologic oncology, clinical trials and robotic surgery. Raj has been contributing to the development of the American Urological Association (AUA) practice guidelines for NMIBC, and he brings to Relmada a broad track record of designing and executing global clinical studies for potential bladder cancer treatments. Raj previously served as Chief Medical Officer at enGene Holdings Inc., and as Global Medical Affairs leader at Johnson and Johnson Innovative Medicine.

"We are very pleased to welcome Raj to Relmada. As we prepare to begin registrational studies, we believe Raj's extensive clinical experience will play a vital role in the NDV-01 program's success," said Sergio Traversa, Chief Executive Officer, Relmada. "Additionally, we have a strong belief that Raj's first-hand understanding of approved bladder cancer therapies and the clinical evidence that is required for widespread physician adoption of new therapies will be a significant asset for Relmada."

"Advancing innovative, bladder-sparing treatments for bladder cancer has been the focus of my career. I joined Relmada because I believe NDV-01 has unique potential to become a class-leading therapy for the treatment of NMIBC," commented Dr. Pruthi, CMO, Relmada. "Current treatments are complex to administer and burdensome for patients. Promising Phase 2 data presented at AUA 2025 showed that NDV-01's gemcitabine/docetaxel (GEM/DOCE) sustained release formulation produced impressive response rates, with favorable overall tolerability, in a simple ready-to-use administration. I am enthusiastic about working with my colleagues at Relmada to achieve our goal of initiating the Phase 3 trial in H1 2026 and bringing NDV-01 to patients with NMIBC as soon as possible."

About Raj S. Pruthi, MD

Raj Pruthi is an accomplished physician, surgeon and clinical scientist with an extensive

career in academic medicine and industry and long publication history. Prior to joining Relmada, Dr. Pruthi was Chief Medical Officer at enGene Holdings Inc., where he led a global team in the development of a registrational therapeutic trial for bladder cancer. Prior to that, he was the Global Medical Affairs Leader, Bladder Cancer and Senior Medical Director, Oncology (Global – Prostate and Bladder Cancer) at Johnson and Johnson Innovative Medicine.

Dr. Pruthi holds multiple leadership roles within the urology community. He is the Chair of the Advisory Council for Urology of the American College of Surgeons and serves on its Board of Governors. He is currently an Adjunct Professor in the Department of Urology at the Donald and Barbara Zucker School of Medicine at Hofstra University/Northwell and Professor, Department of Health System Sciences, Thomas F. Frist, Jr. College of Medicine at Belmont University. Previously, he served as Professor and Chair of the Department of Urology at the University of California at San Francisco and at the University of North Carolina, Chapel Hill.

Dr. Pruthi is a former member of the American Board of Urology/American Urological Association Examination Committee and is Past-President for the Society of Academic Urology. He served on the Guidelines Committee and helped to develop the AUA Guidelines on the Management of NMIBC, and also served on the Bladder Cancer Guidelines Committee of the International Consultation on Urological Diseases.

Dr. Pruthi graduated from Duke University School of Medicine and completed his residency and post-graduate training in Urologic Surgery at Stanford University. He also holds a Master of Health Administration from the University of North Carolina at Chapel Hill.

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

Relmada THERAPEUTICS

Source: Relmada Therapeutics