Relmada Therapeutics Licenses Phase 2 Bladder Cancer Candidate, NDV-01, from Trigone Pharma, Ltd.

Description

NDV-01 is a novel, sustained-release, intravesical gemcitabine/docetaxel, ready-for-use product candidate for the treatment of non-muscle invasive bladder cancer (NMIBC, U.S. prevalence of ~600,000 patients, with ~62,000 newly diagnosed patients annually)

Topline efficacy and safety Phase 2 data expected to be reported at the American Urological Association meeting (AUA), being held April 26-29, 2025 in Las Vegas

NDV-01 has the potential to be a first-line therapy for NMIBC, presenting attractive clinical benefits for clinicians and patients

CORAL GABLES, Fla., March 25, 2025 (GLOBE NEWSWIRE) — Relmada Therapeutics, Inc. (Nasdaq: RLMD, “Relmada”, or “the Company”), a clinical-stage biotechnology company committed to advancing innovative breakthrough therapies, today announced the completion of an exclusive licensing agreement with Trigone Pharma, Ltd. (Trigone) for NDV-01, a novel sustained-release intravesical formulation of gemcitabine and docetaxel (gem/doce) for the treatment of Non-Muscle Invasive Bladder Cancer (NMIBC). The efficacy and safety of the NDV-01 are being evaluated in a Phase 2 study. First data are expected to be reported at the American Urological Association meeting (AUA), being held April 26-29, 2025 in Las Vegas.

“We are delighted to add NDV-01 to our pipeline as we believe it represents an exceptional value-creation opportunity for Relmada and our investors. The drug development expertise of our Team provides flexibility to be opportunistic and consider programs that have the potential to be high-value assets and that can demonstrate proof-of-concept in the near-term, regardless of therapeutic area. NDV-01 is an excellent fit with that profile,” said **Sergio Traversa, CEO** of Relmada Therapeutics.

“We believe Trigone’s novel intravesicular sustained-release formulation could enable NDV-01 to be a first-line therapy for non-muscle invasive bladder cancer, supported by several differentiators including robust published clinical evidence with the gem/doce combination, NDV-01’s good safety profile, easy dosing procedure, and superior drug delivery profile. Together, we believe these features could enable both inpatient and outpatient clinic use, sustained delivery out to 10 days, versus hours for conventional gem-doce delivery, and lead to NDV-01’s rapid and broad adoption,” continued **Dr. Traversa**.

Maged Shenouda, CFO of Relmada added, “We believe NDV-01 is an excellent strategic complement to our recently acquired asset, sepranolone, a unique, Phase 2b-ready neurosteroid with potential applications in the treatment of compulsion-related disorders. The addition of both NDV-01 and sepranolone to our development portfolio achieves our principal objectives of diversifying our pipeline while balancing its risk and upside potential. Our goal is to bring both programs to patients as soon as possible.”

"There is a significant unmet need for effective treatments for patients with non-muscle invasive bladder cancer who don't respond to BCG[1] therapy," said **Yair Lotan, MD, Professor of Urology, and Chief of Urologic Oncology** at UT Southwestern Medical Center at Dallas, Texas. "Based on multiple clinical studies, the combination of gemcitabine and docetaxel has shown impressive efficacy with a manageable safety profile."

"What makes NDV-01 particularly promising is its sustained-release formulation, securing prolonged dwell time and extensive treatment exposure to bladder tumors and enhancing anti-cancer effects. This innovative approach has the potential not only to improve treatment effectiveness but also to improve patient compliance by offering a convenient in-office treatment alternative to current hospital-based therapies, significantly reducing the burden on patients and healthcare systems," said **Dan Touitou, B Pharm, MBA, CEO** of Trigone.

1. *BCG = Bacillus Calmette-Guerin*

About the Clinical Program for NDV-01

NDV-01 is currently being evaluated in a Phase 2, Single-Arm Study (NCT06663137) to assess safety and efficacy in patients with high-grade non-muscle invasive bladder cancer (HG-NMIBC). The study was designed to enroll up to 70 subjects with localized, non-metastatic, HG-NMIBC (ECOG score of 2 of less).

Topline data from the first 20 patients in the study are expected to be presented at the American Urological Association meeting (AUA), being held April 26-29, 2025 in Las Vegas.

Strategic Outlook

Relmada continues to evaluate additional strategic product opportunities to leverage the extensive development capability that the Company has built over the past several years. Relmada anticipates hosting an investor update on NDV-01's next development steps later in 2025.

About the NDV-01 License Agreement

Under the terms of the agreement, Relmada will make a $3.5 million upfront payment and issue 3,017,420 shares of our common stock, which represent 10% of Relmada's outstanding shares, for exclusive worldwide rights to NDV-01, excluding Israel, India and South Africa. (The shares will be locked up for 12 months unless we agree otherwise.) In addition, Relmada will pay up to $200 million in development, regulatory and sales milestones pending successful commercialization. Relmada will also pay a royalty of 3% on any net sales. Following the completion of the ongoing Phase 2 study, Relmada will assume responsibility for NDV-01's development, manufacturing and commercialization.

About NDV-01

NDV-01 is an investigational, innovative sustained-release formulation of two complementary, well-established, chemotherapy agents, gemcitabine and docetaxel (gem/doce). It is designed for intravesical dosing and intended to be an in-office ready-to-use therapy that is administered rapidly and requires no anesthesia or new or dedicated equipment to employ. NDV-01 forms a spherical soft matrix within the bladder that sequesters drug and releases it as the matrix gradually dissolves.

NDV-01's formulation is specifically designed to maximize local drug concentration and prolong exposure to gem/doce, while minimizing systemic toxicity. Unlike conventional intravesical instillations, NDV-01 is designed to avoid peaks and troughs in drug concentration, ensuring a gradual and sustained release of gem/doce over a 10-day period. This approach may potentially improve overall efficacy, reduce side effects, reduce the frequency of dosing and improve patient compliance and outcomes. NDV-01 has the potential to be a first line (1L) therapy for HG-NMIBC, with further potential for use in patients who have failed other therapies, including BCG immunotherapy, and expansion into other NMIBC subtypes, including intermediate-grade disease.

NDV-01 is protected by several patents related to methods of treatment and formulation whose terms go out to 2038.

About Gem/Doce in HG-NMIBC

Gemcitabine and docetaxel (Gem/Doce) therapy in HG-NMIBC has been widely adopted in clinical practice. The highest efficacy has been demonstrated in sequential intravesical treatment (Kates et al., 2020). A literature review suggests that there have been no major side effects reported in published studies or real-world experience. The combination has not been approved by the FDA or EMA.

A Large and Growing Market for NMIBC Therapies

More than 90% of the approximately 83,000 new U.S. cases of urothelial cancer are estimated to be bladder cancer. For the overall bladder cancer population, 5-year survival ranges from 70 to 96% of patients, moving to 6% for patients with advanced disease. Roughly 75% of bladder cancer cases are classified as non-muscle invasive (NMIBC) and approximately 50% of cases are classified as high-grade disease, considered to have increased risk of progression and recurrence. Sources indicate that NMIBC has a 50-75% recurrence rate (over seven years) and that the U.S. prevalence of NMIBC is approximately 450,000 patients.

The US NMIBC market is estimated to be a multi-billion opportunity. Global numbers are higher, in line with projections for significant growth due to the increasing incidence of bladder cancer and the demand for effective, minimally invasive potential therapies like NDV-01. Approved treatment options remain limited (mainly the immunotherapy, BCG, which has been supply constrained for some time), with high recurrence rates leading to frequent re-treatment and progression. Other emerging programs include immunotherapy combinations, single agent chemotherapy formulations and targeted therapies. NDV-01 stands out based on the large body of published data that support the efficacy of treatment with gemcitabine and docetaxel, its ease of administration and potential for durability of action. Expansion beyond first-line treatment into use as a salvage treatment or in other subgroups of NMIBC, including naïve patients, could further increase the opportunity for NDV-01.

About Trigone Pharma Ltd.

Trigone Pharma Ltd. is a privately-held specialty pharmaceutical company focused on the development of a proprietary sustained-release platform designed to enhance the efficacy and safety of established therapeutic agents for urologic diseases into the urinary bladder with clear unmet medical needs.

For more information, please visit https://trigonepharma.com/

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage biotechnology company committed to advancing innovative

breakthrough therapies that have the potential to bring meaningful clinical benefits to targeted patient populations.

Lead investigational program, NDV-01, for High-Grade Non-Muscle Invasive Bladder Cancer, is being evaluated in a Phase 2 study. In addition, preparations are underway to advance sepranolone, a Phase 2b-ready investigational program for compulsion-related disorders including Tourette's Syndrome, into further studies.

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 Phase 2 data to be presented at an upcoming medical conference, potential for Phase 2 data 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 or that future NDV-01 clinical results will be acceptable to the FDA, failure to secure adequate 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.

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