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#143

Prospective Open-Label Study to Evaluate the Safety and Efficacy of Intravesical Sustained-Release Gemcitabine Docetaxel combination (NDV-01) in High-Risk NMIBC: Update with 9-month Complete Response Data

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Introduction

Sequential intravesical gemcitabine and docetaxel (Gem/Doce) represents a promising option to treat patients with high-risk NMIBC. NDV-01 an investigational intravesical agent designed for sustained release of Gem/Doce continuously over a 10-day period. NDV-01 may also help overcome the burdens to patient and to provider (e.g. time toxicity) of traditional Gem/Doce. NDV-01 also does not require a specialized pharmacy or hood.

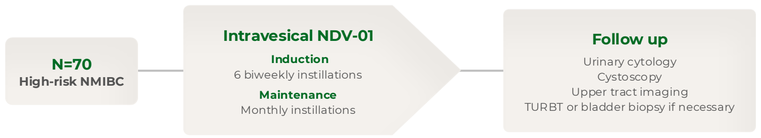
Objective

Evaluate the safety and efficacy of NDV-01 (sustained release of Gem/Doce) in high-risk NMIBC

Methods

The study is a single-arm, open-label trial of NDV-01 in subjects with HG NMIBC. Subjects were given 6 bi-weekly instillations followed by monthly maintenance instillations through month 12. Complete response (CR) was defined as a negative cystoscopy, cytology, and biopsy (if indicated). The first assessment for CR was evaluated at 3 months. Subjects with a non-CR at 3 months, were eligible to be reinduced with an additional 6 bi-weekly course of therapy. Disease assessments for CR were also performed at 6, 9, and 12 months. Twenty-three patients have reached the first disease assessment (3-months follow-up) and are included in the per-protocol efficacy analysis. (Eleven patients are pending their first response assessment.) patients who have received >= 1 treatment are included in the safety analysis.

TRCG-011 study design



Inclusion criteria
High-risk disease with CIS/Tis, Ta, T1 tumors[1,2]
BCG-naive, BCG-unresponsive, intolerant and experienced patients

Purpose
Evaluate the potential of NDV-01 as a safe and effective treatment for patients with high-risk NMIBC

Primary endpoint
Safety
CRR at 12 months

Secondary endpoint
DOR
EFS

Exploratory
PK

Results

- Baseline characteristics of the 36 enrolled subject are shown in Table 1.
- All patients were ECOG 0-1.
- Of the 36 patients who received >= 1 dose of NDV-01, 22 (61%) had a TRAE (62% dysuria, 9% asymptomatic positive urine culture, 7% hematuria).
- No patient had >= Grade 3 TRAE
- No patients discontinued treatment due to AEs.
- No patient had progression to muscle invasive disease.:
- No patient underwent a radical cystectomy.

Table 1: Baseline characteristics (n=29)

Characteristics	n (%)
Gender	
Male	30 (83%)
Female	6 (17%)
Median age (range)	**73 (54-93)**
Median BCG Doses (range)	**6 (0-21)**
BCG-naïve	15 (42%)
BCG exposed	4 (11%)
BCG unresponsive	17 (47%)
Stage	
Pure CIS	3 (8%)
Ta/T1 + CIS	7 (19%)
Ta	21 (58%)
T1	6 (17%)

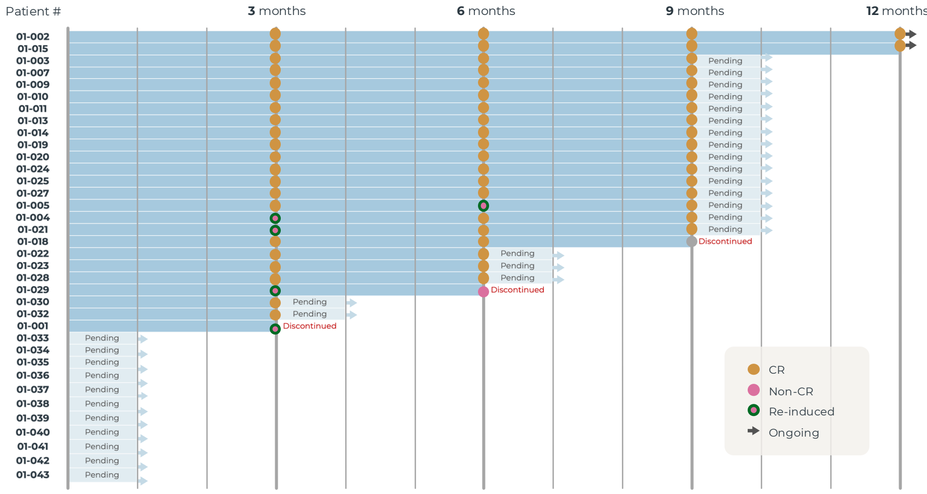


Table 2: Efficacy results

Complete Response	% (n/N)
Anytime	**92%** (23/25)
3 months	**84%** (21/25)
6 months	**87%** (20/23)*
9 months	**85%** (17/20)*

*Includes patients with CR after re-induction. 60% CR rate after re-induction

Conclusions

NDV-01 is a novel sustained formulation of Gem/Doce for intravesical use.

NDV-01 provides excellent 9-month safety and efficacy in patients with high-risk NMIBC.

Data support effectiveness in patients who are BCG-naïve, -exposed and –unresponsive.

Study is ongoing, including 2nd year follow up.

Next steps:

- Relmada is engaged with regulators for a registrational program
- Pivotal studies in both Intermediate-risk and High-risk BCG unresponsive NMIBC populations are planned for 1H2026

Disclosures

This research was sponsored by Relmada Therapeutics, Inc. and was managed by Trigone Pharma Ltd at 1 site in Israel. Dr. Lotan is a paid consultant of Relmada Therapeutics. Dr. Pruthi, Paul Greene, Scott White, Jaqueline Andrews, and Preeti Chirmule are current or former employees of Relmada Therapeutics. Drs. Chertin and Abbas are employees of Shaare Zadek Medical Center, Jerusalem, Israel. Dan Touitou, Avigdor Gordon, Hila Kfir are employees of Trigone Pharma Ltd.

1. The American Cancer Society. Bladder Cancer Stages. American Cancer Society, 12, Mar, 2024. https://www.cancer.org/cancer/types/bladder-cancer/detection-diagnosis-staging/staging.html; **2.** Holzbeierlein, Jeffrey M., et al. "Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment." The Journal of Urology, vol. 211, no. 4, Jan. 2024, pp. 533–38, doi:10.1097/ju.0000000000003846. **CIS**: Carcinoma In Situ; **Ta**: Noninvasive papillary carcinoma; **TI:** Tumor invades lamina propria; **CRR:** Complete Response Rate; **DOR:** Duration of Response. **EFS:** Event Free Survival; **PK:** Pharmacokinetics; **TURBT:** Transurethral resection of bladder tumor; **CR:** Complete response

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