Relmada THERAPEUTICS

# NDV-01 12-Month Phase 2 Data

March 2026

# TRCG-011 for High-Risk NMIBC Study Design

### Inclusion Criteria

- High-risk disease with CIS/Tis, Ta/T 1 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

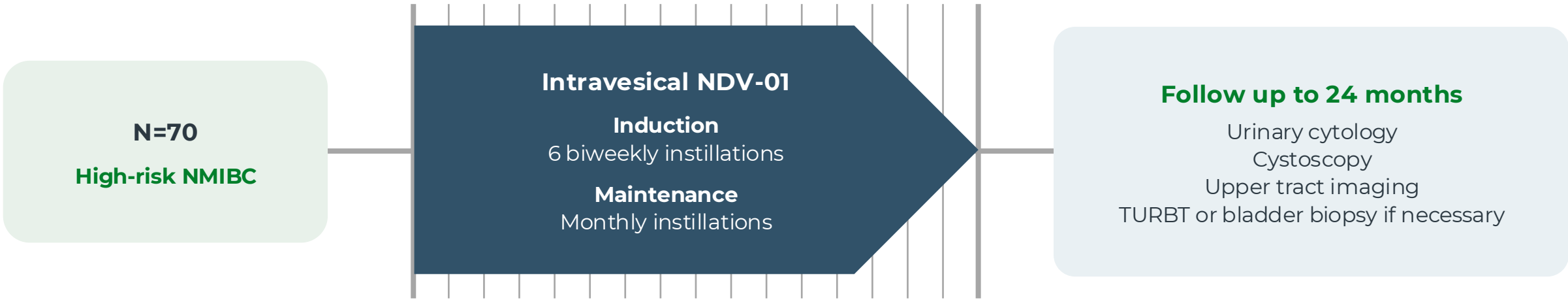
- Safety
- CRR at 12 months

### Secondary Endpoint

- DOR
- EFS

### Exploratory

- PK




**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

# Demographic Data

| Characteristics | N=48 | % |
|---|---|---|
| **Age** | | |
| Median (range) | 75 (52-93) yr | |
| **Sex** | | |
| Male | 42 | 88% |
| Female | 6 | 12% |
| **BCG doses** | | |
| Median BCG doses (range) | 6 (0-23) | |
| **BCG-status** | | |
| BCG-naive | 23 | 48% |
| BCG-exposed | 5 | 10% |
| BCG-unresponsive | 20 | 42% |
| **Stage** | | |
| CIS +/- Ta/T1 | 12 | 25% |
| Ta HG | 29 | 60% |
| T1 HG | 7 | 15% |

# Efficacy and Tolerability

## All Patients (Complete Response)

| | n/N | % |
|---|---|---|
| **Anytime** | 36/38 | 95% |
| **3-month** | 33/38 | 87% |
| **6-month** | 25/29 | 86% |
| **9-month** | 22/26 | 85% |
| **12-month** | 19/25 | 76%<br>KM: 83% |

- No patient had progression to muscle invasive disease
- No patient underwent a radical cystectomy
- 10 patients awaiting 3-month response assessment – Including 3 BCG-unresponsive CIS patients

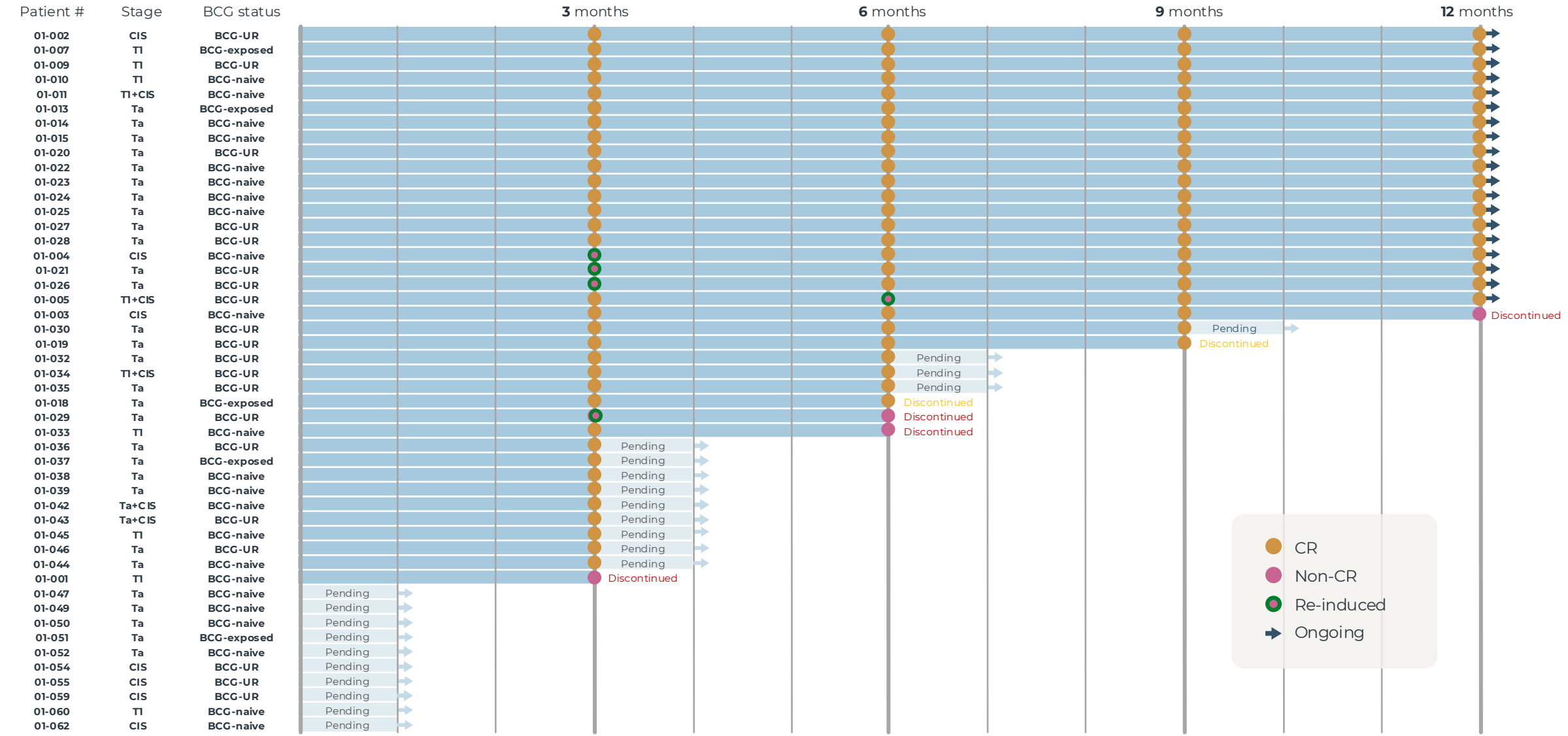
## BCG-UR Subpopulation (Complete Response)

| | n/N | % |
|---|---|---|
| **Anytime** | 16/17 | 94% |
| **3-month** | 14/17 | 82% |
| **6-month** | 12/14 | 86% |
| **9-month** | 10/11 | 91% |
| **12-month** | 8/10 | 80%<br>KM: 84% |

- n = 20 patients dosed in BCG-UR subpopulation
- BCG-UR defined by FDA definition[1]

* Includes patients with CR after re-induction. 60% CR rate after re-induction; **1.** https://www.fda.gov/media/101468/download; **BCG:** Bacillus Calmette-Guérin; **BCG-UR:** BCG-unresponsive; **KM:** Kaplan-Meier analysis

# NDV-01 Provides Durable Response Over Time




**95%** *Anytime* CR rate

**87%** *3-month* CR rate

**86%** *6-month* CR rate

**85%** *9-month* CR rate

**76%** *12-month* CR rate

**CR**: Complete response

# Treatment-Related AE and Tolerability

- **No patient had ≥ Grade 3 TRAE**
- **No patients discontinued treatment due to AEs**
- **Of the 48 patients who received ≥ 1 dose of NDV-01, 30 (61%) had a TRAE**
  - 53% transient uncomfortable urination (dysuria)
  - 8% asymptomatic positive urine culture
  - 8% hematuria

**TRAE:** Treatment-related adverse events; **AE:** Adverse events