Relmada THERAPEUTICS

Advancing Life Changing Therapies

April 2025

Disclosures

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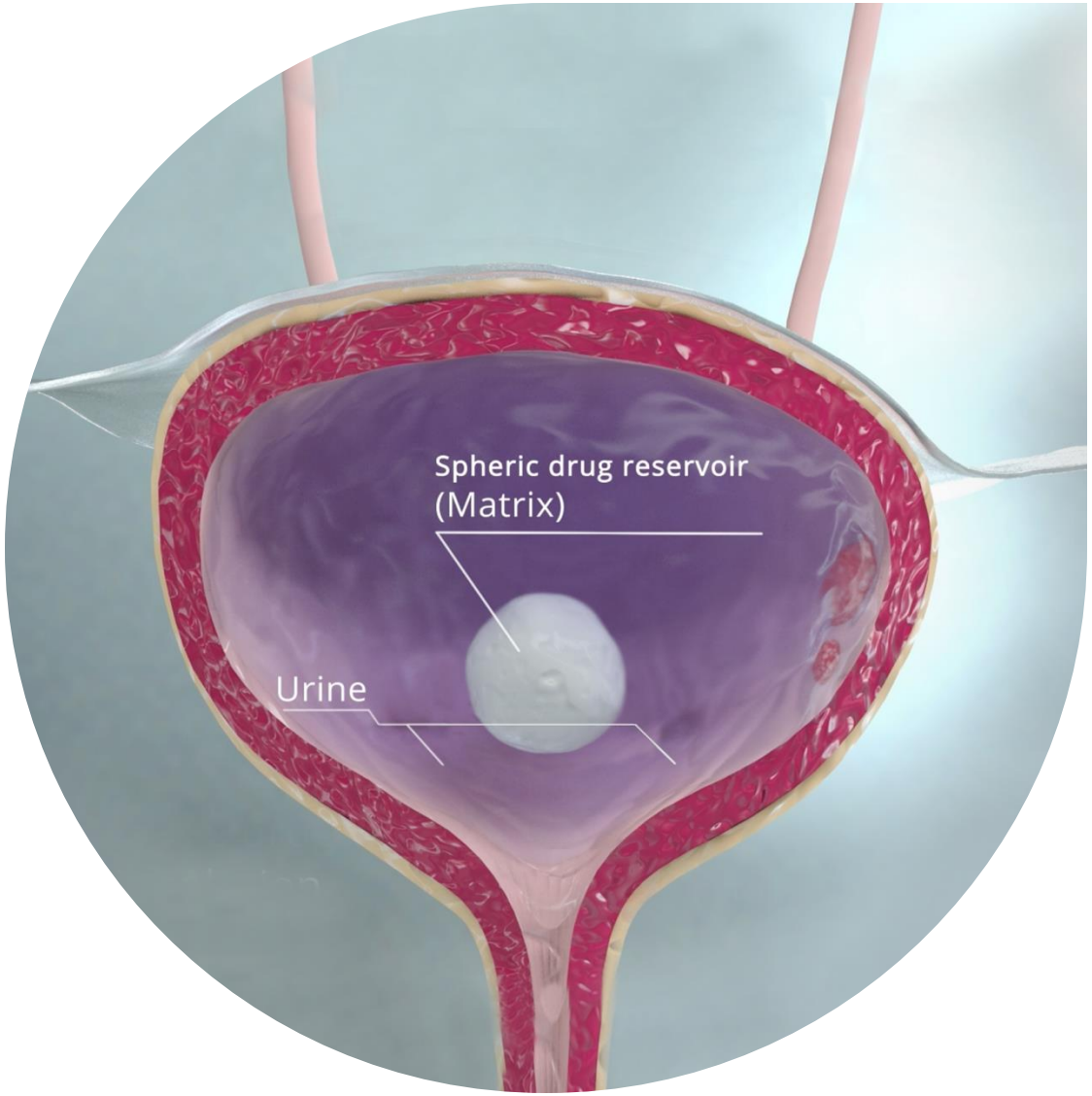
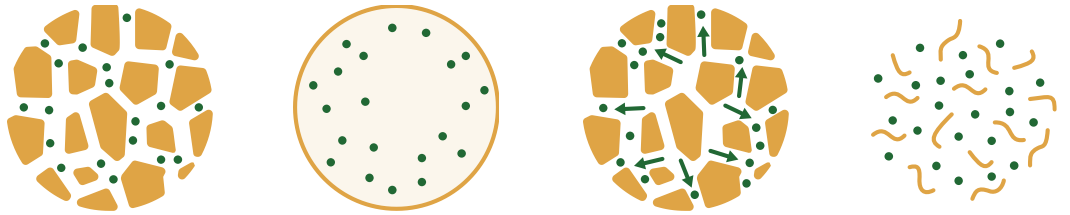
NDV-01 is an investigational intravesical therapy designed for the extended release of gemcitabine and docetaxel

- NDV-01 is an in-situ drug reservoir inside the bladder
- NDV-01 delivers simultaneously a fixed dose combination of gemcitabine (1000mg) and docetaxel (40mg)
- NDV-01 releases a drugs into the bladder continuously for over 10 days
- NDV-01 is biodegradable, gradually disintegrates, and safely excreted in urine
- NDV-01 has been demonstrated in interim Phase 2 data, to be safe and highly tolerable resulting in good patient compliance
- NDV-01 is supplied as prefilled syringe ready for use, easily instilled manually in less then 10 minutes

Targeted intravesical therapy



Bladder-targeted solid matrix drives sustained tumor exposure to the cytotoxic drug combination through controlled release and gradual erosion



Diffusion through pores

Diffusion through the polymer

Osmotic pumping

Erosion

Ongoing TRCG-011 study in high-risk NMIBC patients

An open-label, single-arm single-center study to evaluates safety and efficacy of NDV-01 in HR NMIBC patients

Inclusion criteria

- High-grade disease with Ta, Tis/CIS, T1 tumors
- BCG naïve, 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

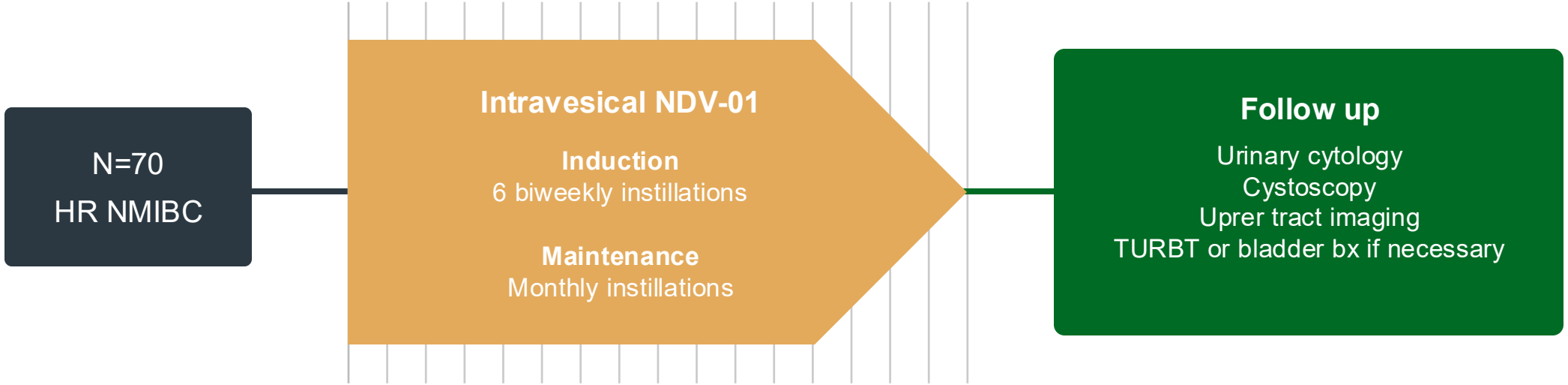
Secondary endpoint

- DOR
- EFS

Other

- PK

Study design



NCT06663137, CRR: Complete Response Rate, DOR: Duration of Response, EFS: Event Free Survival

Demographic data

Characteristics	N=26	%
Age		
Median {IQR}, yr	72.4 {66.9.9-78.3} yr	
Sex		
Male	22	84.6%
Female	4	15.4%
Race		
Caucasian	26	100%
Smoking status		
Never	13	50%
Former	7	27%
Current	6	23%
ECOG PS		
0	19	73%
1	7	27%

Patients and methods

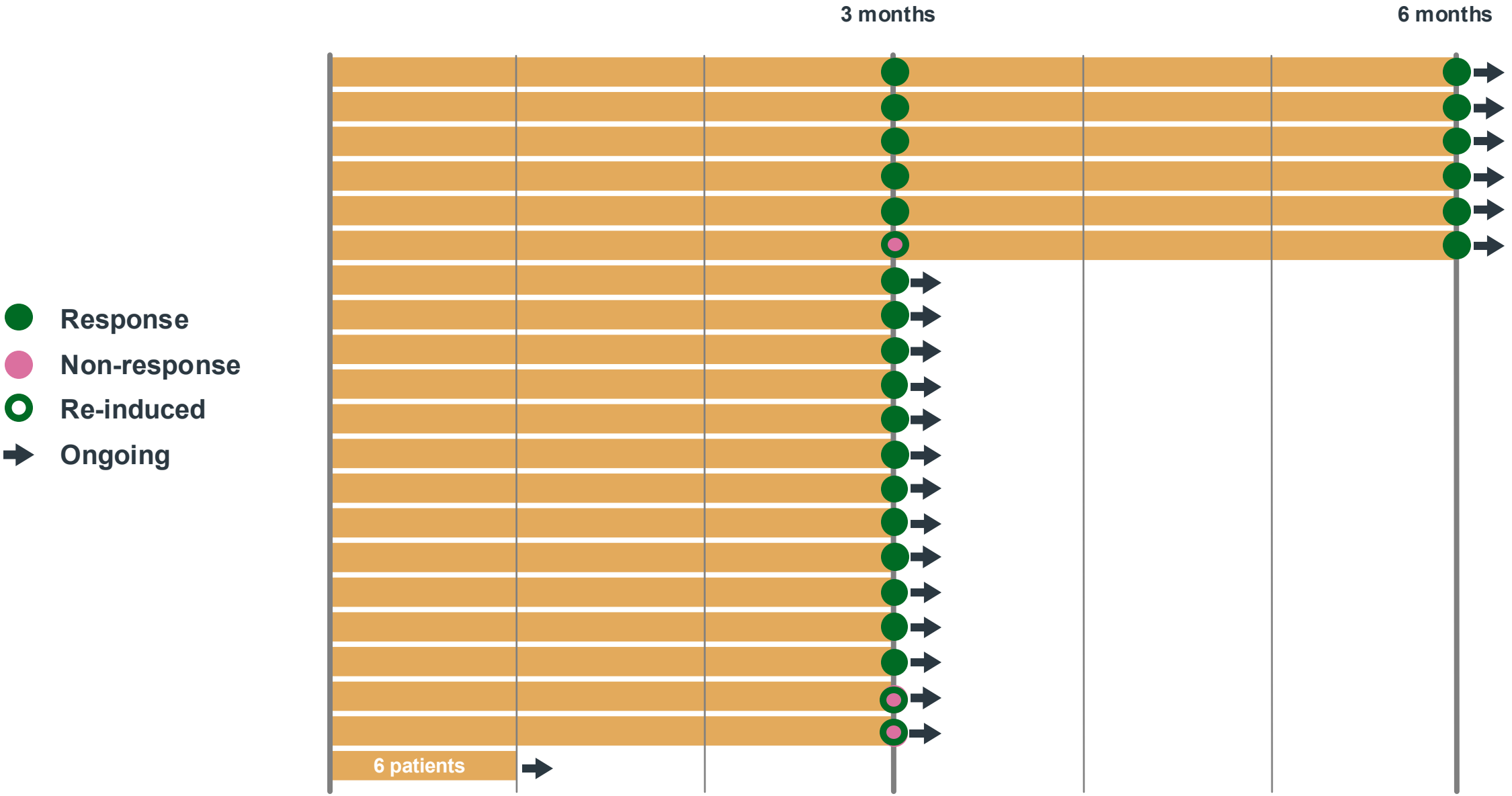
Pathology	N=26	%
CIS	3	11.5%
Ta HG	16	61.5%
T1 HG	7	27.0%

Status	N=26	%
BCG-naïve	9	34.6%
BCG-unresponsive	14	53.9%
BCG-intolerant	3	11.5%

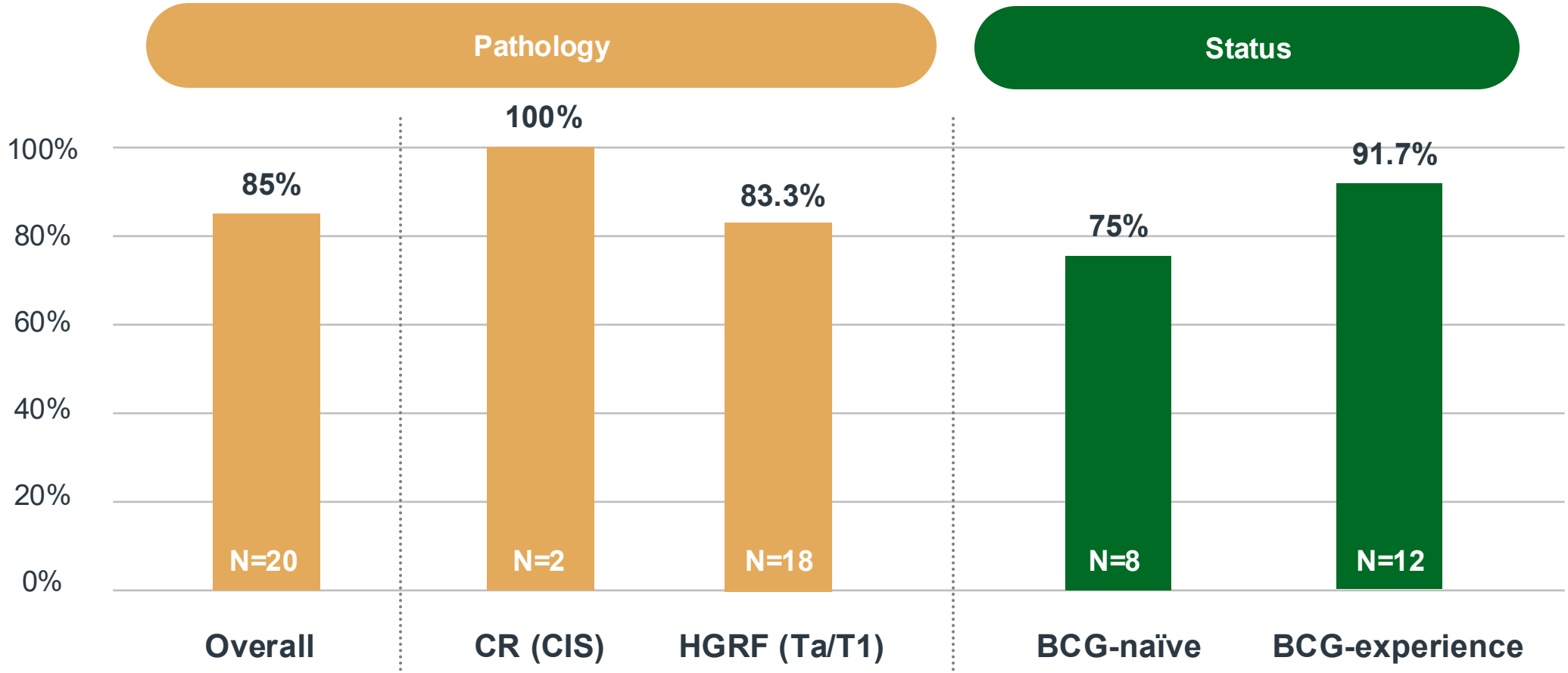
Treatment emergent AE and tolerability (n=26)

- 8 cases (30.7%) G1 dysuria resolved during two days
- 5 cases (19.2%) of G1 unspecific flank pain probably of musculoskeletal origin resolved during 24 hours
- BCG Unresponsive / Intolerant Patients Quality of Life Score improved by 25.8 points

NDV-01 has shown durable response over time

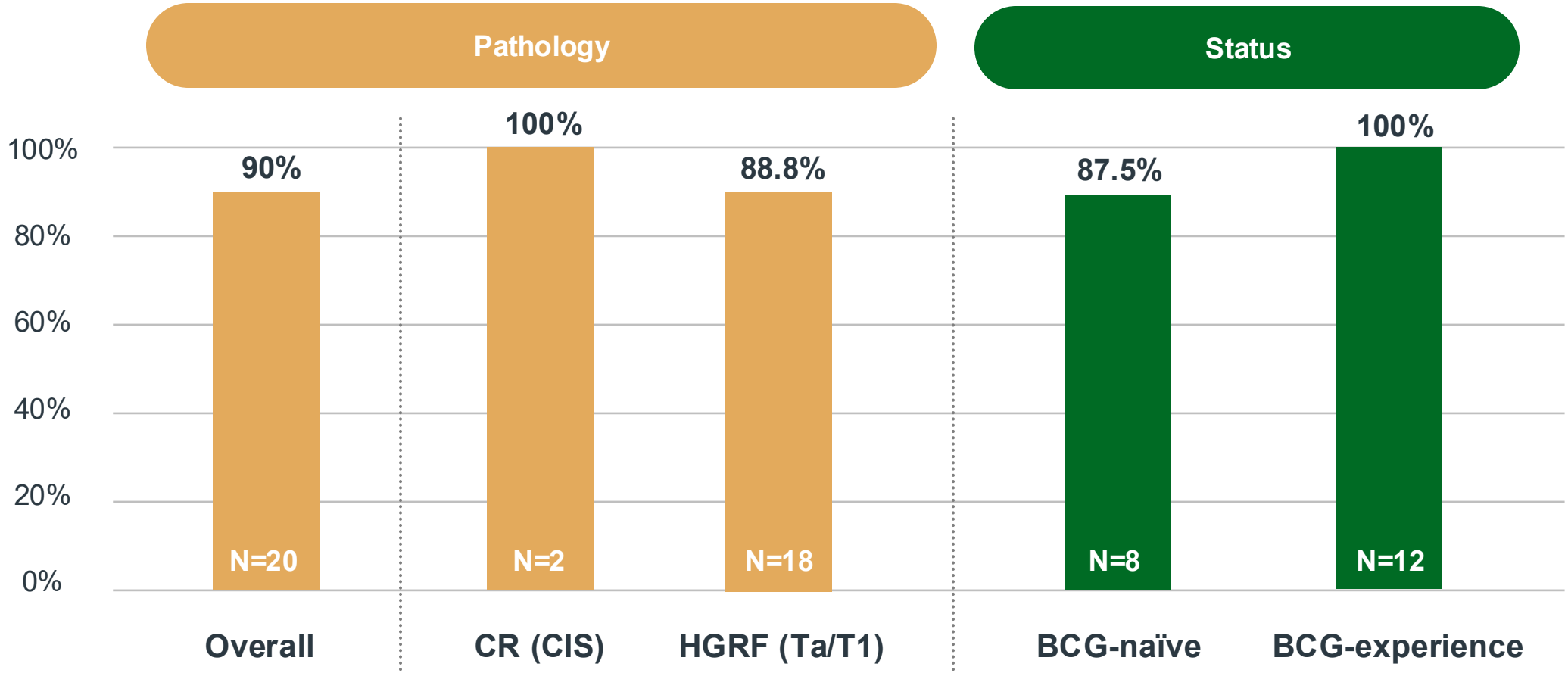


Clinical activity at 3 months time point



NDV-01 demonstrated significant clinical activity at 3 months. The complete response rate in CIS patients was 100%, indicating a strong initial response. Additionally, 83.3% of patients with high-grade papillary disease achieved a high-grade recurrence-free status. These results underscore the therapeutic potential of NDV-01 in managing HR NMIBC and improving patient outcomes.

Clinical activity at any time



NDV-01 demonstrated significant clinical activity at any time. The complete response rate in CIS patients was 100%, indicating a strong initial response. Additionally, 88.8% of patients with high-grade papillary disease achieved a high-grade recurrence-free status. One patient who did not respond in 3 months was re-induced and become a responder at 6 months.

NDV-01 is uniquely designed for busy urology practices

Workflow integration

- GEM/DOCE frequently used and well understood by urologists
- Intravesical administration via standard urinary catheter

Ease of administration for clinicians

- Ready to use in pre-filled syringe presentation
- Doesn’t require dedicated ancillaries
- No biosafety requirements

Ease of administration for patients

- Short administration procedure (10 minutes)
- No need for burdensome removal procedure
- Safe and well tolerated with good patient compliance

Key takeaways

Preparations are underway to advance the NDV-01 program towards registrational studies

1. NMIBC represents a **multi-billion dollar opportunity**, based on a US prevalence of 600,000 patients. Current treatment options are limited

2. Today, Relmada presented **positive initial, three-month Phase 2 data** for NDV-01, an investigational, sustained release formulation of gemcitabine/docetaxol (**GEM/DOCE**)

3. **90% of patients treated with NDV-01 achieved high-grade disease-free status at any time point** following treatment, including **88% HGRFS in papillary patients** and a **100% complete response in patients with CIS**

4. **We believe NDV-01 has the potential to become the class-leading therapy for NMIBC across a wide spectrum of patients based on compelling proof-of-concept for NDV-01 as a bladder-sparing therapy**

5. **We are enthusiastic about advancing this differentiated, ready-to-use GEM/DOCE formulation to improve patient outcomes and expand treatment options in NMIBC**

HGFRS = High-Grade Recurrence-Free Survival; CIS = carcinoma in situ

Thank you