



CORPORATE OVERVIEW

# Unlocking Life Changing Therapies

August 2025



# Disclosures

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 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.

# Targeting life changing treatments with a diversified portfolio

## Strategic pipeline development

Focused on innovative programs with early proof points, near-term milestone(s) and focused markets

## Positive Phase 2a data for NDV-01, for NMIBC

Positive Phase 2a data showed 90% ORR at anytime<sup>2</sup>

Phase 3 trial planned for H1 2026

## Strong team supported by ~\$21 million cash

Proven team with strong development skills

\$21M in cash, with no debt<sup>1</sup>

## Sepranolone, for PWS, backed by POM data

Potential use in Prader Willi syndrome (PWS) backed by positive POM data in Tourette syndrome

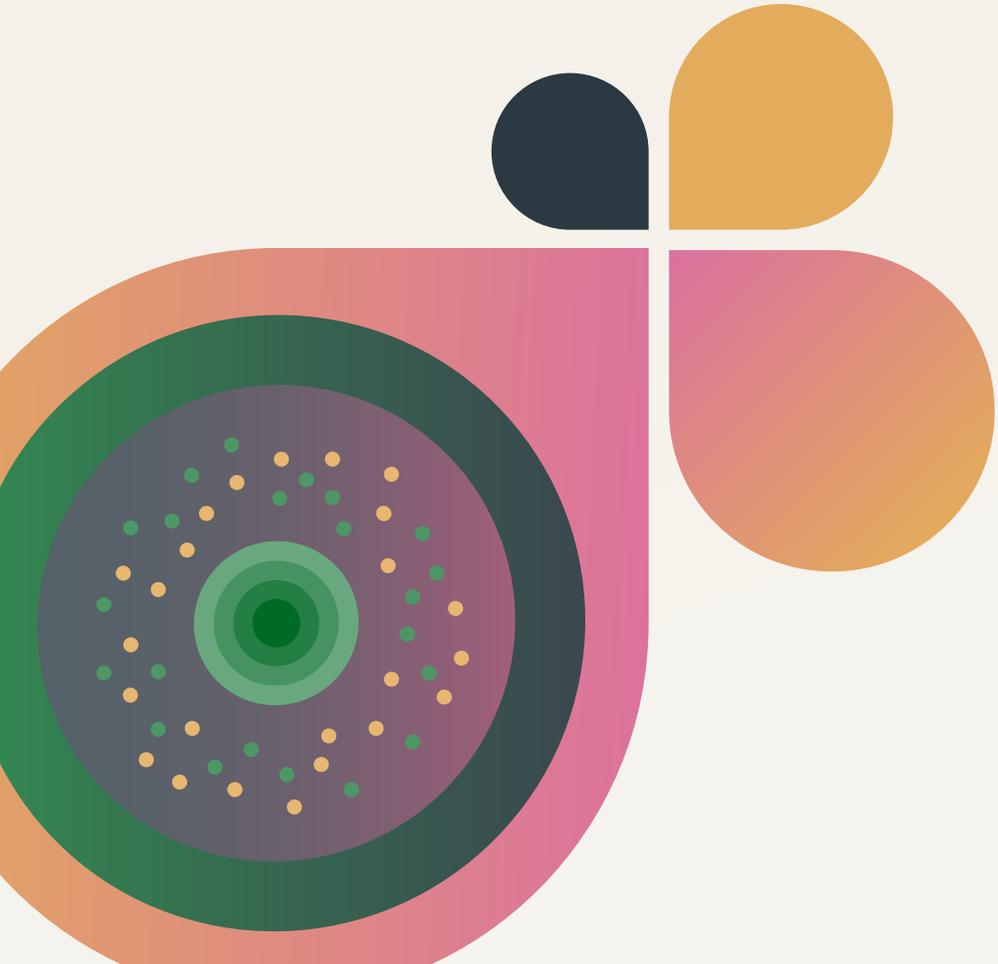
Phase 2b trial planned for H1 2026

# Innovative pipeline of potential high-value assets

Focused on programs with positive proof-of-concept data

Candidate / indication	Phase 1	Phase 2	Phase 3	Potential populations	Status / potential next steps
<p>NDV-01<sup>1</sup></p> <p>Non-muscle invasive bladder cancer (NMIBC)</p>				<p>68K new US patients with NMIBC<sup>2</sup></p> <p>NMIBC US prevalence: 600K patients<sup>3</sup></p>	<p>Q4 2025: 9 Month data</p> <p>Q1 2026: 12 Month data</p> <p>H2 2025: FDA interaction and product supply scale up</p> <p>1H 2026: Initiate Phase 3 study</p>
<p>Sepranolone</p> <p>Prader-Willi Syndrome (PWS)</p>				<p>WW prevalence: 350K to 400K patients<sup>4</sup></p>	<p>Q4 2025: Prep for next studies, including manufacturing</p> <p>H1 2026: Initiate Phase 2b study</p>
<p>Sepranolone</p> <p>Other indications</p>				<p>Including TS, Essential Tremor, OCD and other compulsivity-related indications</p>	<p>YE 2025: Identify next opportunity</p>

<sup>1</sup>. NDV-01: A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce); <sup>2</sup>. Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment"); <sup>3</sup>. Markets, Research And. "Non-muscle Invasive Bladder Cancer (NMIBC) Epidemiology Forecasts to 2034." *GlobeNewswire News Room*, 25 Jan. 2024; <sup>4</sup>. Scheimann, Ann O. "Prader-Willi syndrome: Clinical features and diagnosis." *UpToDate*, edited by Mitchell E Geffner et al., 6 Feb. 2023. **NMIBC**: Non muscle invasive bladder cancer; **WW**: Worldwide; **TS**: Tourette Syndrome; **OCD**: Obsessive-Compulsive Disorder



# NDV-01

A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce) for patients with NMIBC, with positive Phase 2a data<sup>1</sup>

1. American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025  
**NMIBC:** Non-Muscle Invasive Bladder. The graphic is for artistic purposes only, not a factual representation

# Class leading therapy in NMIBC

**NMIBC  
needs new  
treatments**

NMIBC affects >600,000<sup>2</sup> people in the US, with ~67,890<sup>3</sup> new patients each year

**Supported by  
positive  
clinical data**

Use of intravesical Gem/Doce high efficacy in BCG-naïve, -exposed, and -unresponsive disease<sup>4-7</sup>

**NDV-01<sup>1</sup> PK  
data provide  
early proof-  
of-concept**

Potent and durable cytotoxic activity and optimized drug exposure in the bladder

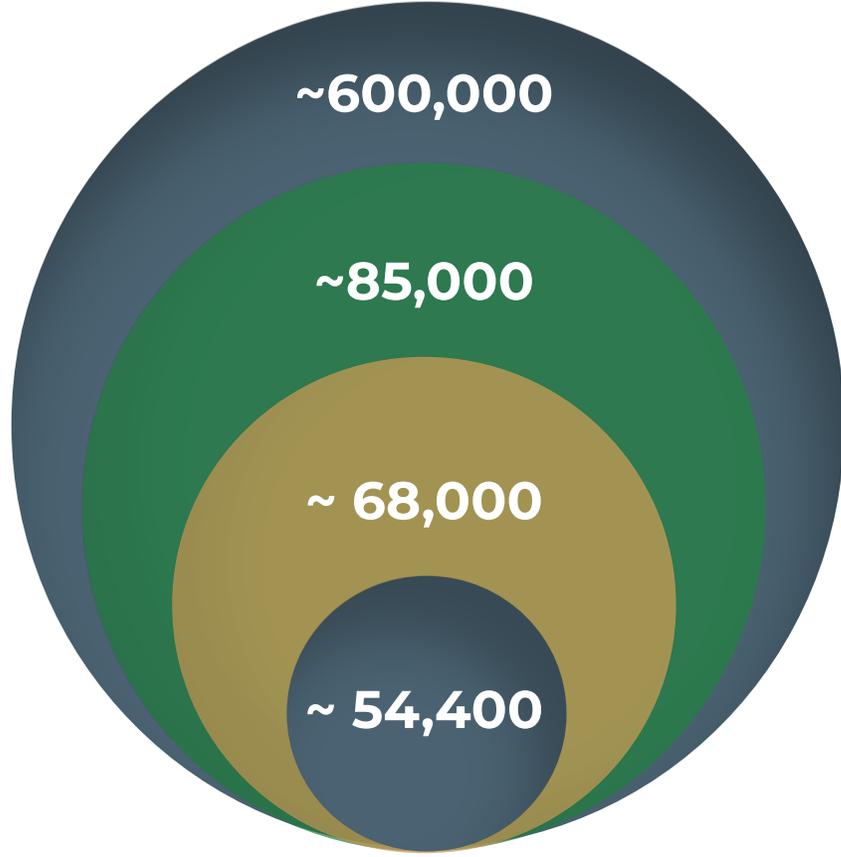
**Phase 2 data  
presented at  
AUA 2025**

Phase 2 data presented at AUA show 90% ORR at any time point<sup>6</sup>

**1.** NDV-01: A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce); **2.** “Non-muscle Invasive Bladder Cancer (NMIBC) Epidemiology Forecasts to 2034.” *GlobeNewswire News Room*, 25 Jan. 2024; **3.** Holzbeierlein et al. (“Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment”); **4.** McElree, Ian M., et al. “Comparison of Sequential Intravesical Gemcitabine and Docetaxel Vs Bacillus Calmette-Guérin for the Treatment of Patients With High-Risk Non-Muscle-Invasive Bladder Cancer.” *JAMA Network Open*, vol. 6, no. 2, Feb. 2023, p. e230849; **5.** Chevuru PT, McElree IM, Mott SL, Steinberg RL, O'Donnell MA, Packiam VT. Long-term follow-up of sequential intravesical gemcitabine and docetaxel salvage therapy for non-muscle invasive bladder cancer. *Urol Oncol.* 2023 Mar;41(3):148.e1-148.e7; **6.** American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025; **7.** Kawada T, Yanagisawa T, Araki M, Pradere B, Shariat SF. Sequential intravesical gemcitabine and docetaxel therapy in patients with nonmuscle invasive bladder cancer: a systematic review and meta-analysis. *Curr Opin Urol.* 2023 May 1;33(3):211-218. **NMIBC:** Non-Muscle Invasive Bladder; **BCG:** Bacillus Calmette-Guérin; **ORR:** Objective Response Rate; **AUA:** American Urological Association; **PK:** Pharmacokinetic

# NMIBC opportunity<sup>1</sup> — high prevalence and high recurrence rate

Supply issues for prior BCG-standard and gaps in care driving NMIBC innovation



**US prevalence of NMIBC<sup>1</sup>**  
(non-muscle invasive bladder cancer)

**New Bladder cancer cases<sup>2</sup>**  
70-96% 5-year overall survival, 6% with advanced disease<sup>3</sup>

**NMIBC cancer cases (75-80% of bladder cancers)<sup>4, 6</sup>**  
50-80% recurrence rate (over five years)<sup>5</sup>

**Intermediate-risk and high-risk have increased risk of recurrence and progression (Intermediate-risk represents 45%<sup>6, 7</sup> and high-risk represents 35%<sup>7</sup> of NMIBC cases)**

<sup>1</sup>. Markets, Research And. "Non-muscle Invasive Bladder Cancer (NMIBC) Epidemiology Forecasts to 2034." *GlobeNewswire News Room*, 25 Jan. 2024; <sup>2</sup>. The American Cancer Society medical and editorial content team. "Key Statistics for Bladder Cancer." American Cancer Society, [www.cancer.org/cancer/types/bladder-cancer/about/key-statistics.html](http://www.cancer.org/cancer/types/bladder-cancer/about/key-statistics.html); <sup>3</sup>. American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025; <sup>4</sup>. Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment"); <sup>5</sup>. Białek, Łukasz. "EORTC Bladder Cancer Recurrence and Progression Calculator." *Omni Calculator*, 1 Aug. 2024, [www.omnicalculator.com/health/eortc-bladder-cancer](http://www.omnicalculator.com/health/eortc-bladder-cancer); <sup>6</sup>. Seo, Munseok, and James R. Langabeer II. "Demographic and Survivorship Disparities in Non-muscle-invasive Bladder Cancer in the United States." *Journal of Preventive Medicine and Public Health*, vol. 51, no. 5, Aug. 2018, pp. 242-47; <sup>7</sup>. Nielsen, Matthew E., et al. "Trends in Stage-specific Incidence Rates for Urothelial Carcinoma of the Bladder in the United States: 1988 to 2006." *Cancer*, vol. 120, no. 1, Oct. 2013, pp. 86-95, doi:10.1002/cncr.28397. **NMIBC**: Non-Muscle Invasive Bladder; **BCG**: Bacillus Calmette-Guérin

# NMIBC patient care journey

1

Physicians diagnose suspected cases of bladder cancer using cystoscopy and cytology. (Most common presenting symptom is blood in urine.)

2

Treatment begins with TURBT (transurethral resection of bladder tumor) surgery to stage, risk-stratify, and treat patients.

3

Following surgery, patients with HR-NMIBC typically receive intravesical BCG as primary treatment

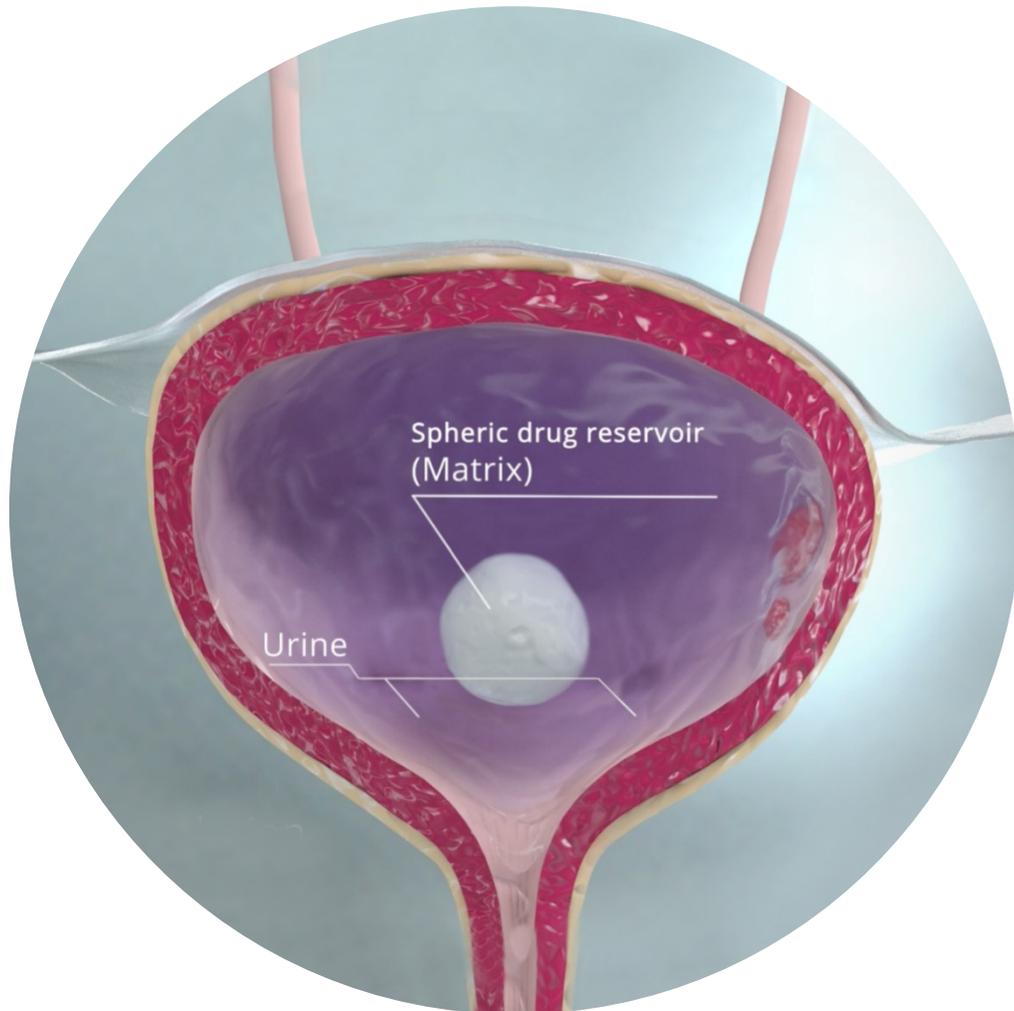
4

Regular cystoscopies and urine cytology (up to every 3 months) are used to monitor patients and assess for recurrence

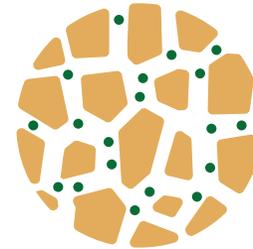
5

Following BCG therapy, for patients with recurrent disease, alternative intravesical treatments are used, including chemotherapies such as Gem/Doce

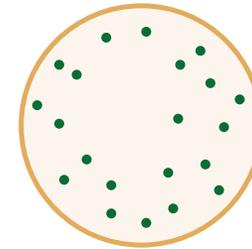
# Targeted intravesical therapy



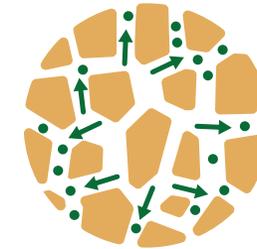
**Bladder-targeted solid matrix enables prolonged tumor exposure to the cytotoxic drug combination via multiple delivery modalities**



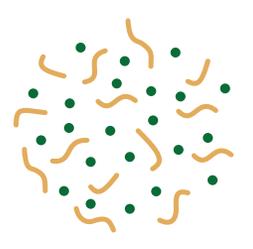
**Diffusion through pores**



**Diffusion through the polymer**



**Osmotic pumping**



**Erosion**

# NDV-01's innovative approach

**< 5 minutes** procedure  
in the doctor's office

An in-situ drug  
reservoir made with  
GRAS polymers  
instilled inside the  
bladder

Followed by the two  
cytotoxic drugs  
1000mg gemcitabine  
then 40mg docetaxel  
(Gem/Doce)

**> 10 days** of drug exposure

The reservoir and the  
drugs form a soft  
matrix inside  
the bladder

Ten-day sustained  
tumor exposure to  
the drugs potentially  
enhances efficacy  
while reducing  
systemic toxicity

Fully clears the body  
in **12-14 days**

Reservoir matrix  
disintegrates, and is  
safely excreted via  
the urine

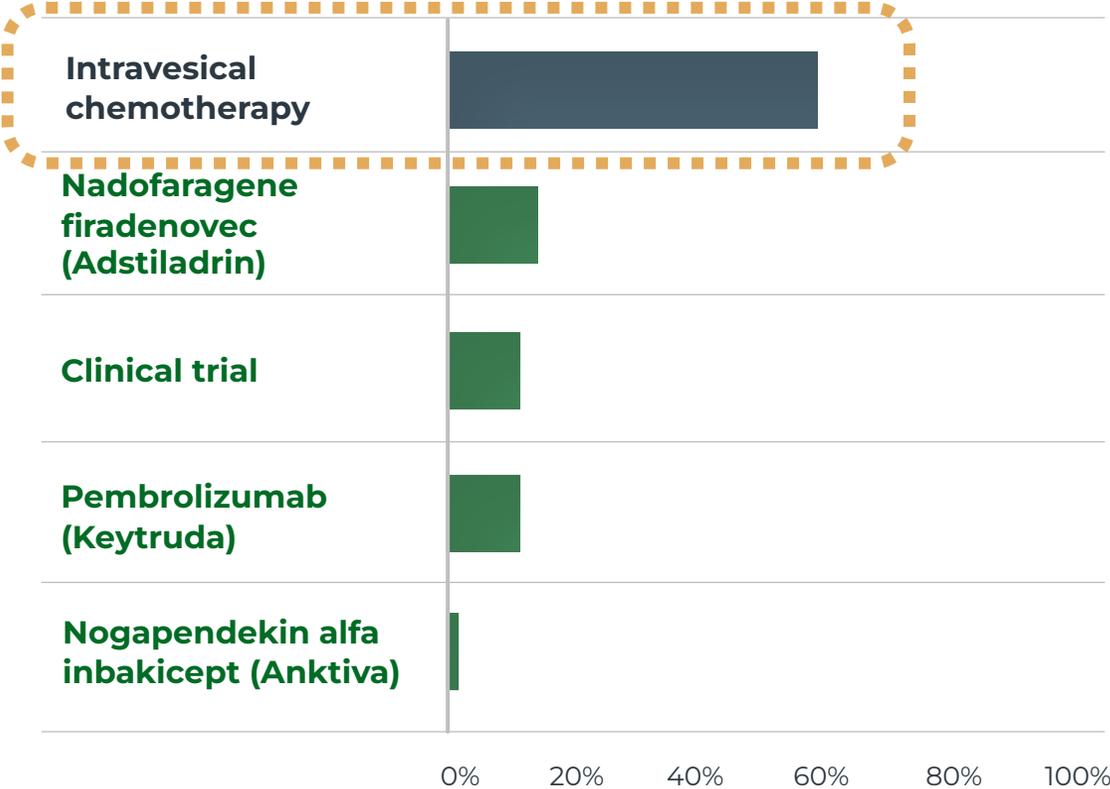
# Gem/Doce combination has been embraced by the urologic oncology community

- Effective salvage treatment for patients who have **failed or are intolerant to BCG** with reported 2-year RFS ~50%<sup>1, 2, 3</sup>
- Gem/Doce is an effective alternative first-line agent in **high-risk BCG naïve** patients with 2-year RFS of 82%<sup>4</sup>
- Gem/Doce use expanding into **intermediate-risk and low-grade tumors** with reported 2-year RFS of 70-80%<sup>5, 6</sup>
- Gem/Doce **avoids/delays radical cystectomy**<sup>7, 8</sup>
- Large ongoing cooperative “BRIDGE” study (n=870) evaluating Gem/Doce combination v. BCG (NCT05538663)

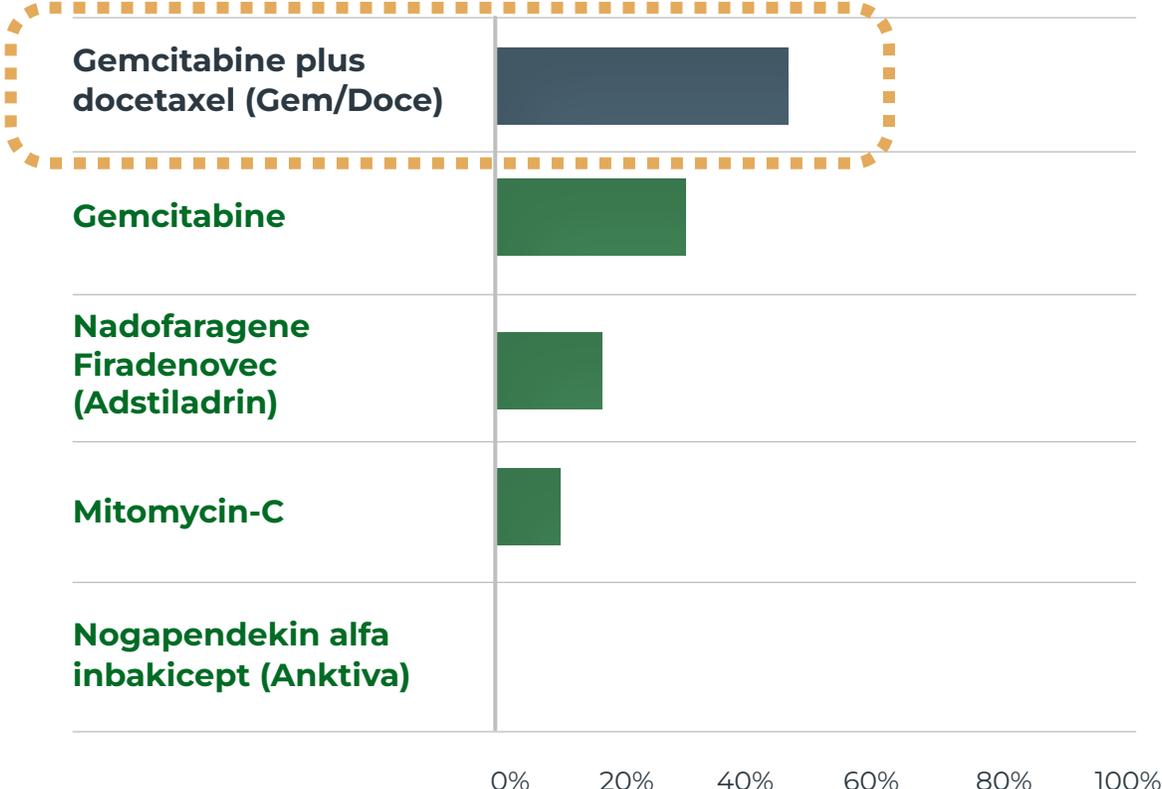
1. Steinberg RL, Thomas LJ, Brooks N, et al. Multi-Institution Evaluation of Sequential Gemcitabine/Docetaxel as Rescue Therapy for NMIBC. J Urol. 2020; 2. Garneau CA, Marcotte N, Lacombe L, et al. Salvage therapy for BCG failure with intravesical sequential Gem/Doce in patients with recurrent NMIBC. Can Urol Assoc J J Assoc Urol Can. 2024; 3. Yim K, Melnick K, Mott SL, et al. Sequential intravesical gemcitabine/docetaxel provides a durable remission in recurrent high-risk NMIBC following BCG therapy. Urol Oncol. 2023; 4. McElree IM, Steinberg RL, Martin AC, et al. Sequential Intravesical gemcitabine/docetaxel for BCG-Naïve High-Risk NMIBC. J Urol. 2022; 5. McElree IM, Orzel J, Stubbee R, et al. Sequential intravesical gemcitabine/docetaxel for treatment-naïve and previously treated intermediate-risk NMIBC. Urol Oncol. 2023; 6. Tan WS, McElree IM, Davaro F, et al. Sequential Intravesical Gemcitabine/Docetaxel is an Alternative to BCG for the Treatment of Intermediate-risk NMIBC. Eur Urol Oncol. 2023; 7. Chevuru PT, McElree IM, Mott SL, Steinberg RL, O'Donnell MA, Packiam VT. Long-term follow-up of sequential intravesical gemcitabine and docetaxel salvage therapy for NMIBC. Urol Oncol. 2023; 8. Narayan VM, Boorjian SA, Alemozaffar M, et al. Efficacy of Intravesical Nadofaragene Firadenovec for Patients With BCG-Unresponsive NMIBC: 5-Year Follow-Up From a Phase 3 Trial. J Urol. 2024. **RFS:** Relapse Free Survival; **BCG:** Bacillus Calmette-Guérin; **NMIBC:** Non-muscle-Invasive Bladder Cancer

# Gem/Doce combination stands out in *Urology Times* survey<sup>1</sup>

What is your preferred treatment for patients with BCG-unresponsive NMIBC?



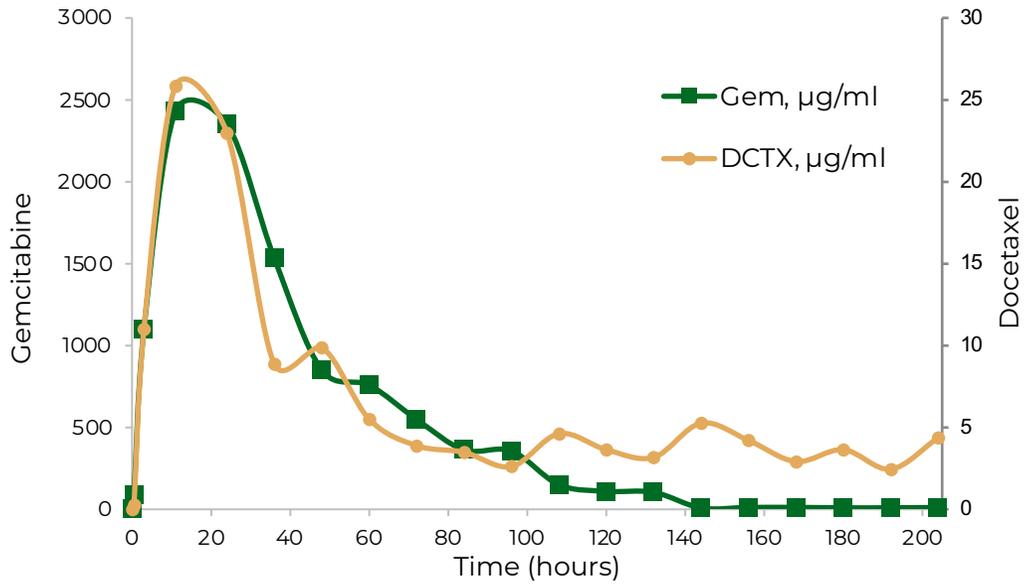
When selecting intravesical therapy after BCG-unresponsive NMIBC, which agent do you most commonly use?



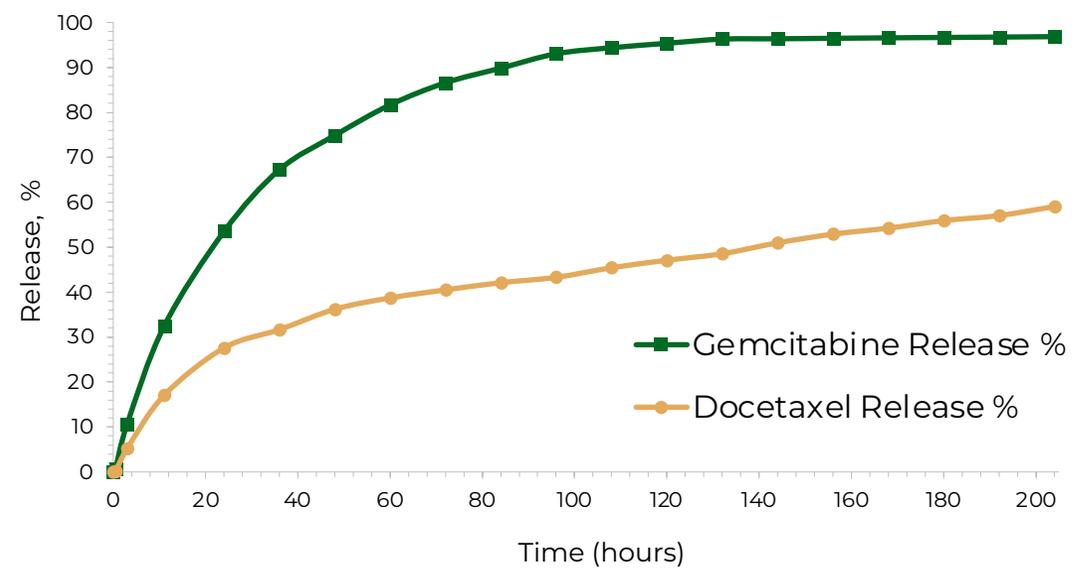
<sup>1</sup> Derived from Urology Times: Survey on Treatment Patterns and Preferences in Non-Muscle Invasive Bladder Cancer, June 2025, based on responses from 42 practicing physicians (Saylor, Benjamin P. "Survey: New NMIBC Treatments Face Slow Uptake." *Urology Times*, 17 July 2025, [www.urologytimes.com/view/survey-new-nmibc-treatments-face-slow-uptake](http://www.urologytimes.com/view/survey-new-nmibc-treatments-face-slow-uptake).)

# NDV-01 In-vitro drug concentrations show continuous & optimized drug release in the bladder

NDV-01 Gem/Doce concentration over time



NDV-01 cumulative release profile



In-vitro profiles demonstrate stable and predictable drug levels, minimizing peaks and troughs associated with systemic side effects.

Controlled drug exposure can potentially enhance anti-tumor activity while reducing the frequency of administration, enabling biweekly dosing.

Experimental overview: 12g NDV-01 with 10% gemcitabine, 0.25% docetaxel formulation was instilled into 10ml artificial urine (AUF) and kept in an orbital shaker incubator at 37°C, 20 rpm. The AUF sample was withdrawn twice a day and replaced by fresh AUF. The drug concentration in the AUF was quantitatively determined by HPLC.



**Study TRCG-011  
high-risk NMIBC  
patients**

An open-label, single-arm, single-center study to evaluate safety and efficacy of NDV-01 in HR NMIBC patients (NCT06663137)

# Study design

## Inclusion criteria

- High-risk disease with CIS/Tis, Ta, T1 tumors<sup>1,2</sup>
- 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

## Exploratory

- PK



<sup>1</sup>. 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>; <sup>2</sup>. 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; **T1:** 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=29	%
<b>Age</b>		
Median (range)	73 (54-93) yr	
<b>Sex</b>		
Male	24	83%
Female	5	17%
<b>BCG doses</b>		
Median BCG doses (range)	7 (0-18)	
<b>BCG-status</b>		
BCG-naive	12	41%
BCG-exposed	4	14%
BCG-unresponsive	13	45%
<b>Stage</b>		
CIS	3	10%
CIS + Ta/T1	4	14%
Ta HG	18	62%
T1 HG	4	14%

# Treatment emergent AE and tolerability

**Of the 28 patients  
who received  $\geq 1$   
dose of NDV-01, 21  
(72%) had a TRAE**

77% dysuria  
9% asymptomatic  
positive urine culture  
4% hematuria

**No patient had  $\geq$   
Grade 3 TRAE**

**No patients  
discontinued  
treatment due to  
AEs**

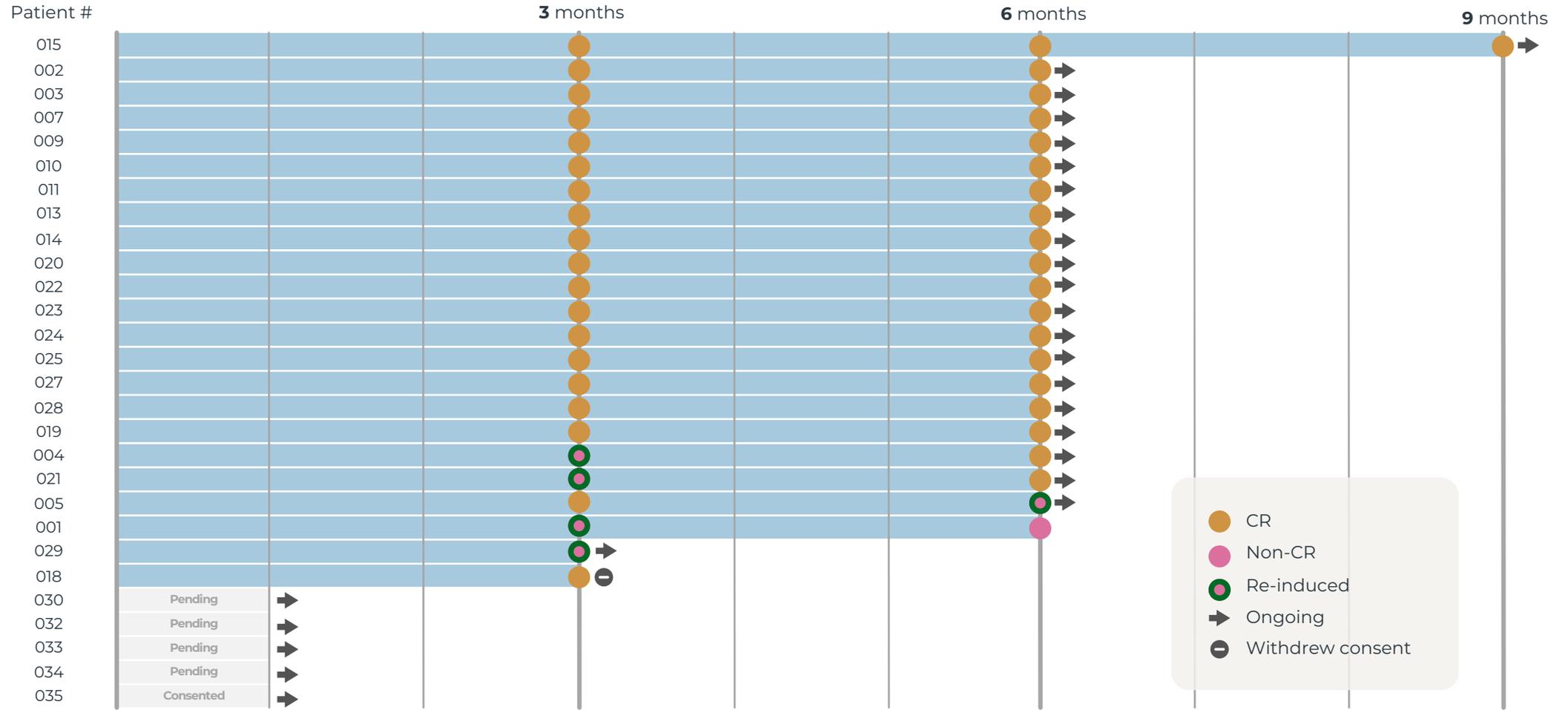
# Efficacy

Complete response	n/N	%
Anytime	21/23	91%
3-month	19/23	83%
6-month	19/21 <sup>1</sup>	90%

One subject has reached the 9-month assessment and had a CR  
No patient had progression to muscle-invasive disease  
No patient underwent a radical cystectomy

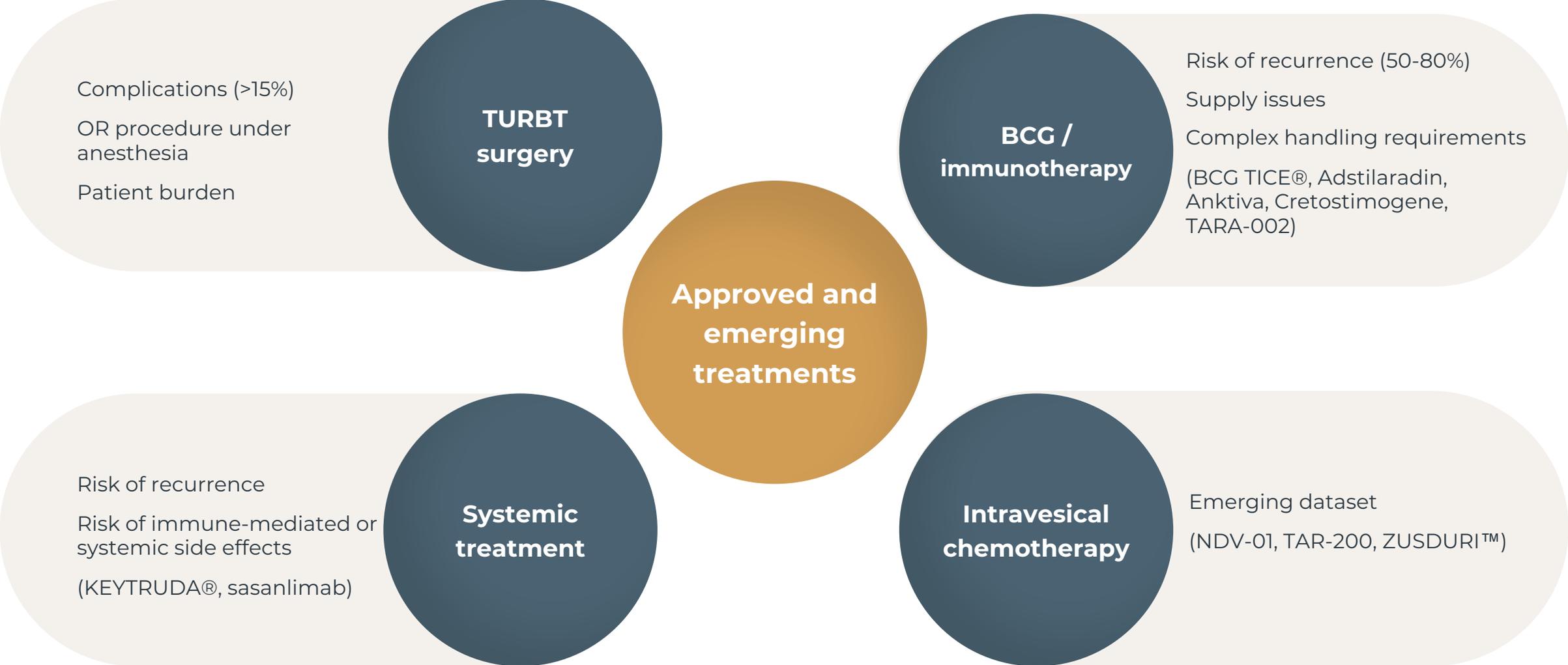
<sup>1</sup>. Includes 2 patients with CR after re-induction. 4 subjects underwent re-induction due to non-CR at 3 months, of which 3 had a 6-month assessment (1 pending). Of these 3 subjects, 2 had a 6-month CR (66% CR rate after re-induction)

# Demonstrated durable response over time



**91%** Anytime CR rate      **83%** 3-month CR rate      **90%** 6-month CR rate      Pending completion

# Overview of NMIBC treatment landscape



# NDV-01: a differentiated intravesical approach

Product / product profile	NDV-01	TAR-200	ZUSDURI™
<b>Sponsor</b>	Relmada	Johnson & Johnson	UroGen
<b>Active Agent</b>	Gemcitabine/docetaxel (Gem/Doce)	Gemcitabine	Mitomycin C
<b>NMIBC subtype</b>	High-risk or intermediate-risk	High Risk	Low grade, intermediate risk
<b>Phase</b>	Phase 2	Phase 3	FDA approved
<b>Dosing Format</b>	Sustained-release hydrogel	Indwelling silicone delivery system	Reverse-thermal hydrogel
<b>Presentation</b>	Pre-filled syringe ready for intravesical delivery	Catheter-based insertion; cystoscopic removal	In-office dosing kit requires in-office reconstitution under chilled conditions
<b>Requires device removal?</b>	No	Yes, via cystoscope <sup>1</sup>	No

# Competitive advantages

**NDV-01 is an investigational intravesical therapy designed for the extended release of gemcitabine and docetaxel (Gem/Doce)**



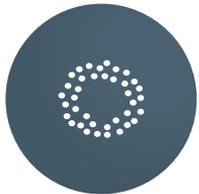
## Ready for use

NDV-01 is supplied as prefilled syringe ready for use, easily instilled via catheter in **< 5 minutes**



## Convenience

Patients are treated **in doctors' office**



## Sustained release

NDV-01 releases Gem/Doce inside the bladder **continuously for 10 days**, resulting in sustained tumor exposure and meaningful improvement in patient outcome



## Based on an existing effective treatment

Gem/Doce, **an existing, effective and well understood** treatment for NMIBC, is frequently used by urologists



## Safely excreted

NDV-01 polymer biodegradable, gradually disintegrates, and is safely excreted via the urine

# Expecting to advance NDV-01 towards registration-track studies in H1 2026

2H  
2025

## Phase 2 data updates

Results from 9 and 12 month follow-up

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Q4  
2025

## FDA Engagement

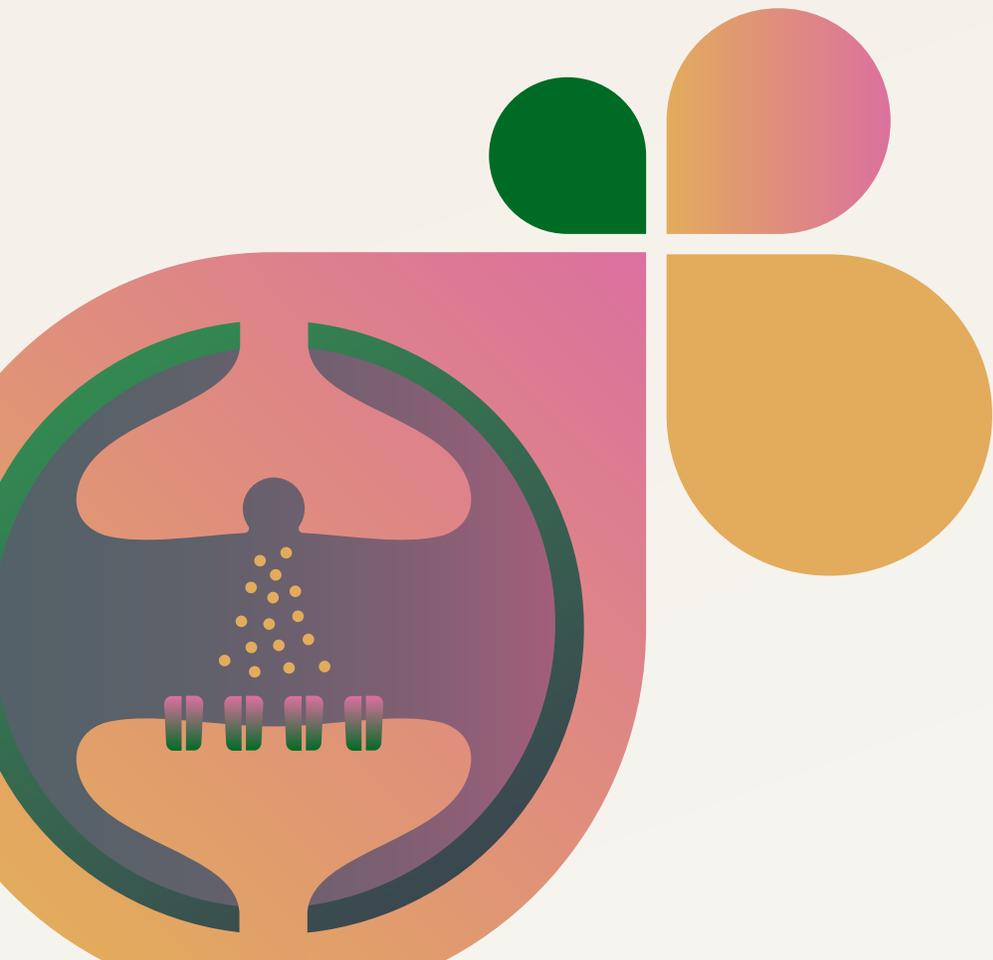
Including planned FDA interactions and manufacturing

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H1  
2026

## Initiate Phase 3 study

Target population to be confirmed through FDA discussions



# Sepranolone

A novel candidate, with potential to overcome the challenges of current therapies for compulsivity disorders

The graphic is for artistic purposes only, not a factual representation

# Sepranolone has the potential to normalize GABA<sub>A</sub> receptor activity

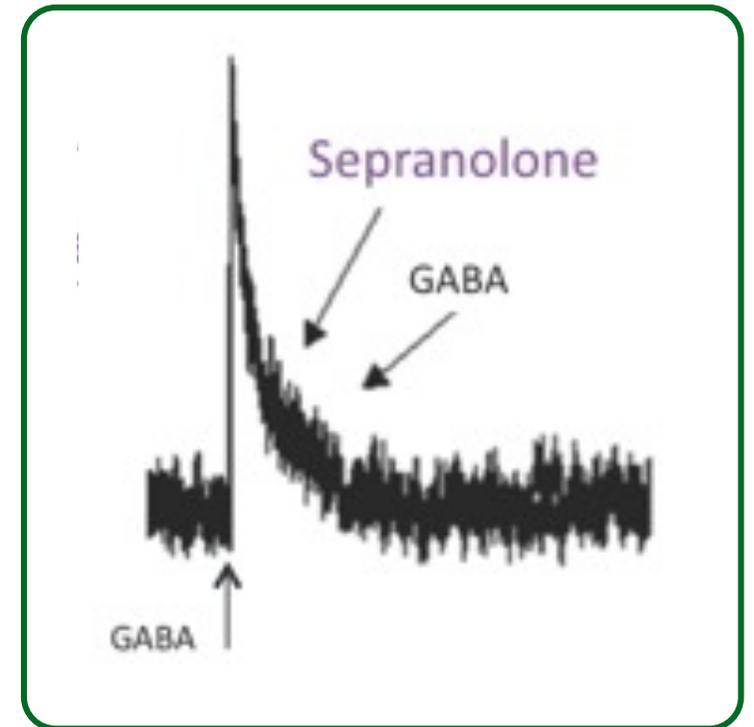
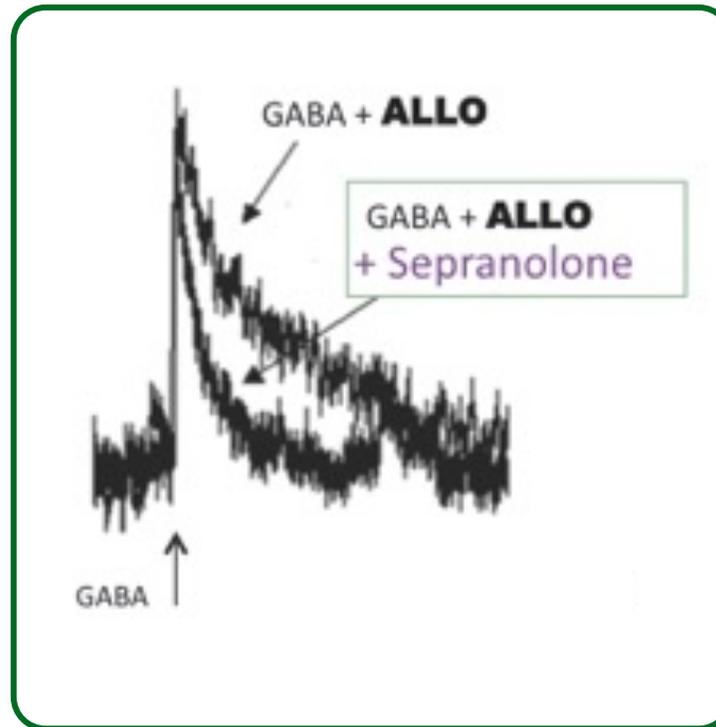
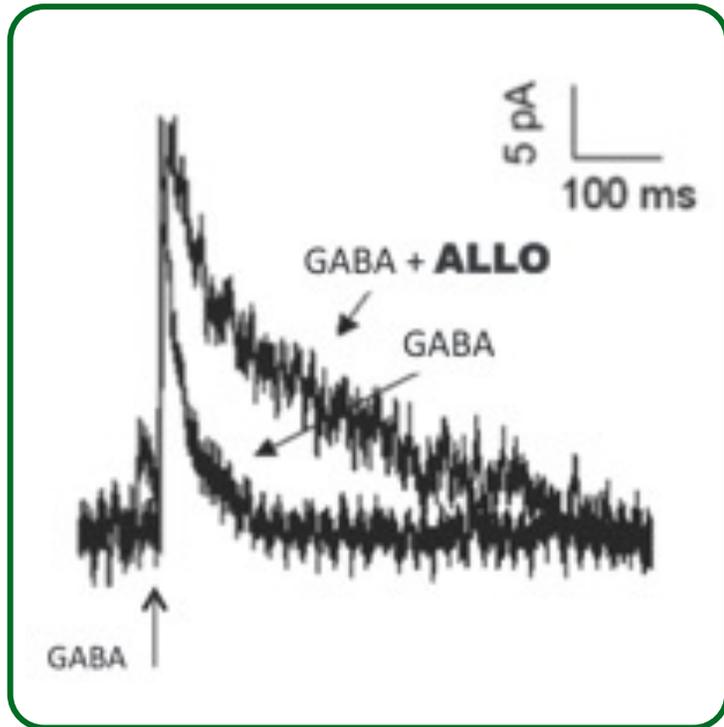
**GABA**  
(**γ-aminobutyric acid**) is the primary neurotransmitter, involved in anxiety and compulsive disorders

**Allopregnanolone (ALLO)** typically enhances GABA<sub>A</sub> calming effects

**In some individuals, ALLO exacerbates anxiety and compulsivity**

**Sepranolone normalizes GABA<sub>A</sub> receptor activity** without interfering in GABA signaling

# Sepranolone normalizes GABA<sub>A</sub> receptor activity (in vitro)



Endogenous Sepranolone attenuates ALLO-enhanced GABA-activation of the GABA<sub>A</sub> receptor<sup>1</sup> in a dose-dependent manner, with with high specificity<sup>2</sup>

Sepranolone does not interfere with GABA signaling

<sup>1</sup> Strömberg, J., et al. "Neurosteroid Modulation of Allopregnanolone and GABA Effect on the GABA-A Receptor." *Neuroscience*, vol. 143, no. 1, Aug. 2006, pp. 73–81, doi:10.1016/j.neuroscience.2006.07.031;

<sup>2</sup> Lundgren et al, Brain Research 2003. Patch clamp experiment to evaluate receptor activity using electric current over the synaptic cleft. GABA<sub>A</sub>: Y-aminobutyric acid type A; ALLO: Allopregnanolone ©2025 Relmada - All rights reserved | 26

# Topline sepranolone safety and efficacy data<sup>1</sup>

Sepranolone treatment produced a **28% drop in tic severity** (p=0.051), with consistent positive impact on secondary endpoints

**Positive results across secondary Quality of Life measures**, using widely accept scoring systems including the Gilles de la Tourette Syndrome Quality of Life total score (69% increase)

**No CNS off-target or systemic side effects** were observed

# Positive Phase 2 data and unique MOA give sepranolone broad potential

## Prader-Willi Syndrome

Genetic disorder often defined by persistent hunger and overeating

Global prevalence 350-400K people<sup>1</sup>

## Tourette Syndrome

Neurological disorder characterized by repetitive, involuntary tics, with childhood onset

US prevalence 350-450K children<sup>3</sup>

## Essential Tremors

Neurological disorder that causes involuntary, rhythmic shaking. Primarily notice during voluntary movements

US prevalence 6.4 MM people<sup>2</sup>

## Obsessive-Compulsive Disorder and related disorders

OCD is characterized by intrusive, unwanted thoughts (obsessions) and repetitive behaviors (compulsions)

US prevalence 8.2M people<sup>4</sup>

<sup>1</sup>. Scheimann, Ann O. "Prader-Willi syndrome: Clinical features and diagnosis." UpToDate, edited by Mitchell E Geffner et al., 6 Feb. 2023, [www.uptodate.com/contents/prader-willi-syndrome-clinical-features-and-diagnosis#H12](http://www.uptodate.com/contents/prader-willi-syndrome-clinical-features-and-diagnosis#H12); <sup>2</sup>. Crawford, Stephen, et al. "How Many Adults in the US Have Essential Tremor? Using Data From Epidemiological Studies to Derive Age-specific Estimates of Prevalence (4458)." *Neurology*, vol. 94, no. 15\_supplement, Apr. 2020, doi:10.1212/wnl.94.15\_supplement.4458; <sup>3</sup>. Tinker, Sarah C., et al. "Estimating the Number of People With Tourette Syndrome and Persistent Tic Disorder in the United States." *Psychiatry Research*, vol. 314, June 2022, p. 114684, doi:10.1016/j.psychres.2022.114684; <sup>4</sup>. International OCD Foundation. "International OCD Foundation | Who Gets OCD?" International OCD Foundation, 16 Dec. 2024, [iocdf.org/about-ocd/who-gets-ocd](http://iocdf.org/about-ocd/who-gets-ocd). **PWS:** Prader-Willi syndrome; **ET:** Essential Tremor; **OCD:** Obsessive Compulsive Disorder

# Impact on compulsivity could open the door to use in Prader-Willi Syndrome

**Prader-Willis Syndrome is an unmet need**

Prader-Willi syndrome (PWS) affects 350,000 to 400,000 people worldwide<sup>1</sup>

**Sepranolone is a first-in-class candidate**

Sepranolone's ability to target the GABA<sub>A</sub> and impact compulsivity disorders

**Planning a Phase 2 study in 1H 2026**

Advancing manufacturing scale-up and preparations to meet with FDA

# Expecting to advance sepranolone towards Phase 2 studies in Prader-Willi Syndrome in H1 2026

Q4  
2025

## Phase 2 PWS preparations

Including planned FDA interactions and further development of product supply

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H1  
2026

## Initiation of Pilot Phase 2 study in Prader-Willi Syndrome

Focus on evaluating early proof-of-concept



# Corporate summary

# Financial overview

**\$20.6  
million**

**Cash, cash  
equivalents &  
short-term  
investments**

**~33.2  
million**

**Common shares  
outstanding  
(45.1 million as  
converted)**

**Unlevered  
balance  
sheet**

**No outstanding  
debt**

# NDV-01 and sepranolone poised to make important progress in 2025-2026

Q4 2025	<b>NDV-01</b>	Planned FDA interactions, manufacturing build-out
Q4 2025	<b>Sepranolone</b>	Planned FDA interactions, product supply expansion
H1 2026	<b>NDV-01</b>	Initiate registration-track study
H1 2026	<b>Sepranolone</b>	Initiate pilot PWS study



**Thank you!**

# Appendix

# Sepranolone has the potential to normalize GABA<sub>A</sub> receptor activity

