Relmada THERAPEUTICS

Unlocking Life Changing Therapies

Corporate Overview | November 2026

Disclosures

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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 fail to continue to deliver positive results supporting further development, potential for clinical trials to fail to deliver statistically and/or clinically significant evidence of efficacy and/or safety, failure of interim or 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, risks related to the manufacture of NDV-01, including chemistry, manufacturing and controls (CMC) activities and reliance on third-party manufacturers, potential changes to the design of the Phase 3 SPECTRUM program, including as a result of updated clinical practice guidelines or FDA feedback, the Company’s cash runway and sufficiency of the Company’s cash resources and uncertainties inherent in estimating the Company’s cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials, 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.

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The Promise of NDV-01: Gem/Doce Reimagined™

Novel, patented, sustained release, ready-to-use Gem/Doce co-formulation administered in <5 minutes

- Strong physician familiarity with conventional Gem/Doce
- Sustained release for up to 10 days extends local drug exposure
- Biodegradable matrix without added procedural or tolerability burden
- Ready-to-use (RTU) product designed for ease of adoption and broad utilization

Interim P2 data[1] in HR NMIBC build on over a decade of compelling clinical evidence with conventional Gem/Doce

94%	**Anytime CR[1]**
77%	**12-month landmark CR[1]**
0%	**Grade ≥ 3 TR AEs & DCs[1]**
100%	**Progression Free Survival[1]**
100%	**Cystectomy Free Survival[1]**

FDA aligned Phase 3 program with two independent registrational cohorts

SPECTRUM
NDV-01 Phase 3 Program

Two Independent Registrational Cohorts

2UC: 2L HR BCG-UR CIS ± Ta/T1 (single arm; N=87)

IRA: IR Adjuvant vs. Observation (randomized 1:1; N=276, under review)

Exploratory Cohort

2UP: 2L HR BCG-UR Ta/T1 w/o CIS (single arm; N=50)

NDV-01 holds the potential to be the best-in-class intravesical treatment across the NMIBC disease spectrum

1. Interim results from ongoing phase 2 trial in HR NMIBC through Month 12. **CR:** Complete response; **BCG:** Bacillus Calmette-Guérin; **BCG-UR:** BCG-Unresponsive; **NMIBC:** Non-muscle invasive bladder cancer; **DC:** Discontinuations; **RTU:** Ready to use; **DC:** Discontinuation; **TRAE:** Treatment-related adverse event

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Anticipated Milestones

Focused on programs with positive proof-of-concept data

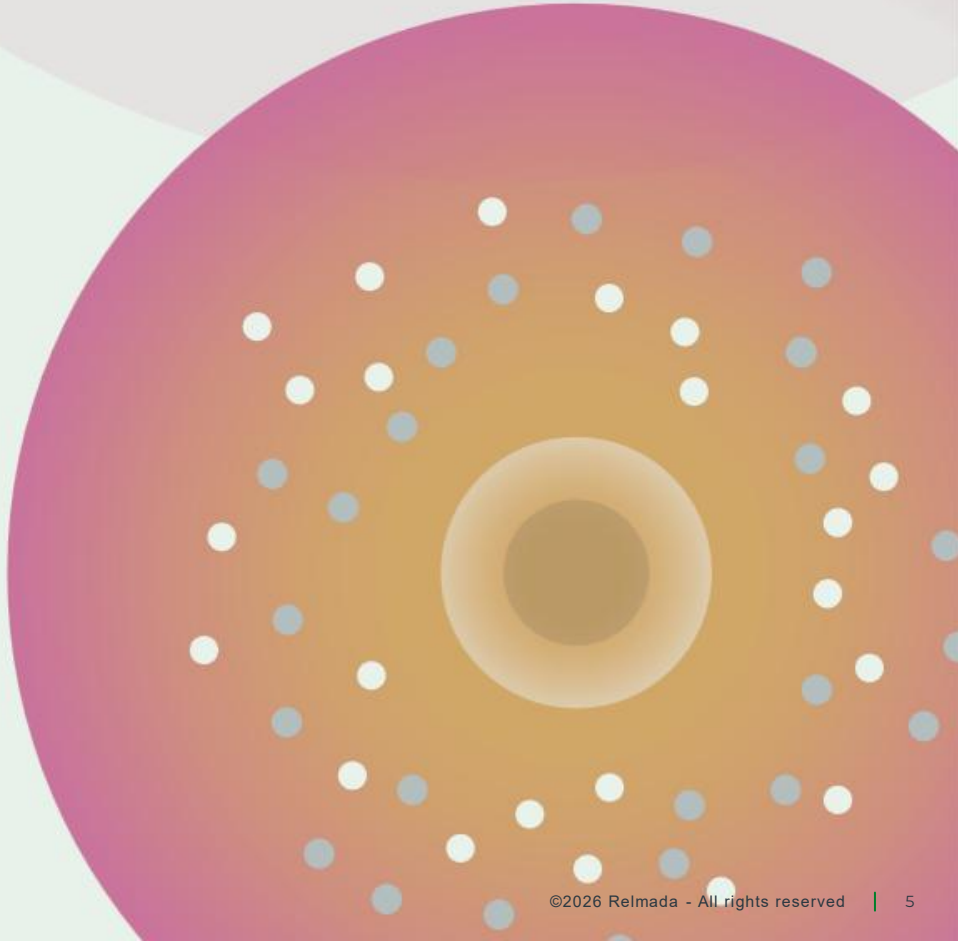
Candidate / Indication	Phase 1	Phase 2	Phase 3	Status / Potential Next Steps
NDV-01[1] High-Risk NMIBC (Study TRGC-011)				**4Q26:** Continued enrollment and long-term follow-up
NDV-01 2L HR BCG-Unresponsive CIS ± Ta/T1 (SPECTRUM Cohort 2UC)[2]			★ Upon IND Clearance	**YE26:** Submit the NDV-01 IND **Upon IND Clearance:** Initiate SPECTRUM Phase 3 registrational Cohort 2UC
NDV-01 Intermediate-Risk NMIBC Adjuvant (SPECTRUM Cohort IRA)			★ Upon IND Clearance	**Upon IND Clearance:** Initiate SPECTRUM Phase 3 registrational Cohort IRA
NDV-01 2L HR BCG-Unresponsive Ta/T1 w/o CIS (SPECTRUM Cohort 2UP)[3]		★ Upon IND Clearance		**Upon IND Clearance:** Initiate SPECTRUM Phase 2 exploratory Cohort 2UP
Sepranolone Prader-Willi Syndrome (PWS)		★ Upon IND Clearance		**YE26:** Submit the Sepranolone IND **Upon IND Clearance**: Initiate Phase 2b study

1. NDV-01: A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce); **2.** BCG-Unresponsive patients with CIS +/- Ta/T1 disease; Phase 3 Cohort 2UC is a registrational cohort intended for regulatory approval. **3.** BCG-Unresponsive patients with high-grade Ta/T1 disease. Cohort 2UP is an exploratory cohort and not intended for regulatory approval. **NMIBC:** Non-muscle invasive bladder cancer; **BCG:** Bacillus Calmette-Guérin; **2L:** Second Line.

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NDV-01

A novel, sustained-release, intravesical co-formulation of gemcitabine/docetaxel (Gem/Doce) being developed for patients with NMIBC



NMIBC: Non-muscle invasive bladder cancer. The graphic is for artistic purposes only, not a factual representation

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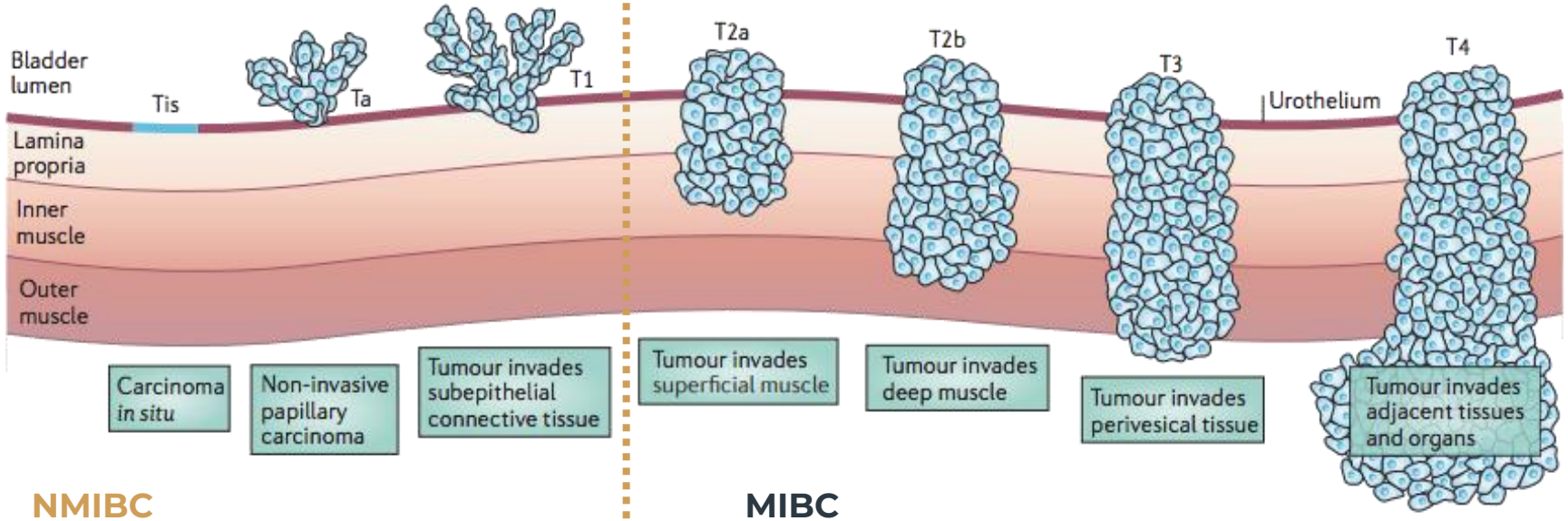
Our Focus: Non-Muscle Invasive Bladder Cancer (NMIBC)

75% of new cases

Non-muscle invasive

25% of new cases

Muscle-invasive



NMIBC

- Papillary tumors: non-invasive projections from the bladder surface
- Carcinoma in situ (CIS): flat, aggressive cancer that is often unresectable

MIBC

- Tumors have invaded bladder muscle with or without lymph node involvement
- Tumors may have spread to nearby organs but are not growing into the pelvic or abdominal wall

Flaig TW, Spiess PE, Abern M, et al. Bladder Cancer, Version 1.2026, NCCN Clinical Practice Guidelines In Oncology. *J Natl Compr Canc Netw*. 2026;24(5):186-203. doi:10.6004/jnccn.2026.0022

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Intravesical Chemotherapy is a Recommended Treatment in Intermediate and High-Risk NMIBC

Low Risk

Surveillance

Unmet Needs

- Repeated surveillance

Intermediate Risk
(~60k/yr including recurrent)

Surveillance ± perioperative chemo

Intravesical Chemotherapy

Unmet Needs

- High recurrence rate
- Repeat TURBTs
- Progression to HR disease

High Risk
(~25k/yr incident patients)

BCG

Preferred first option

Intravesical Chemotherapy (mitomycin, gemcitabine, sequential gemcitabine/docetaxel)

Intravesical Immunotherapy*

Systemic Immunotherapy ± Intravesical BCG

4 FDA-approved therapies in 1L after BCG failure, but nothing approved in 2L or later

Cystectomy

Unmet Needs

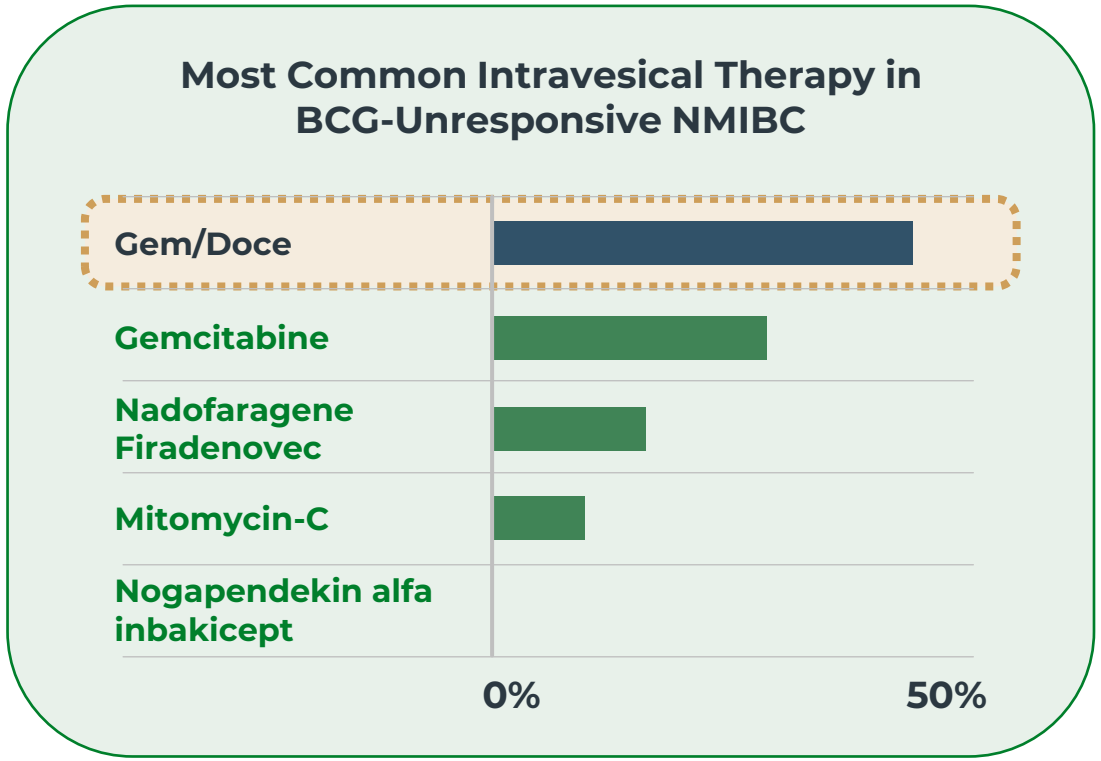
- Risk of progression to muscle-invasive and metastatic disease
- High morbidity of radical cystectomy
- Limited efficacy and durability of bladder-sparing therapies
- High treatment burden (tolerability, frequency, duration, procedural)
- Complex workflow integration

Based on NCCN Guidelines Version 3.2026, FDA product labels; * Intravesical immunotherapy includes gene therapy that causes interferon production; **NMIBC:** Non-muscle invasive bladder cancer; **BCG:** Bacillus Calmette Guérin; **TURBT:** Trans Urethral Resection of Bladder Tumor; **CR:** Complete Response; **RFS:** Recurrence Free Survival; **1L:** First Line; **2L:** Second Line

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Conventional Gem/Doce is Favored by Urologists Despite Operational Challenges

HCPs and Patients Choose Gem/Doce



Operational Inefficiencies

Up to 4-Hour Workflow

Specialized pharmacy preparation

↓

Administer Gemcitabine

↓

~60-120 min dwell time

↓

Drain bladder and administer Doce

↓

~90-120 min dwell time

Additional Challenges

Specialized Pharmacy

Requires hazardous drug hood and personal protect equipment

Limited Drug Exposure

Suboptimal dwell time inside the bladder reduces efficacy

Academic Concentration

Treatment remains largely limited to academic centers meeting prerequisites

1. 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. **NMIBC:** Non-muscle invasive bladder cancer; **Gem/Doce**: Gemcitabine plus Docetaxel

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NDV-01 Addresses Significant Issues with Conventional Gem/Doce

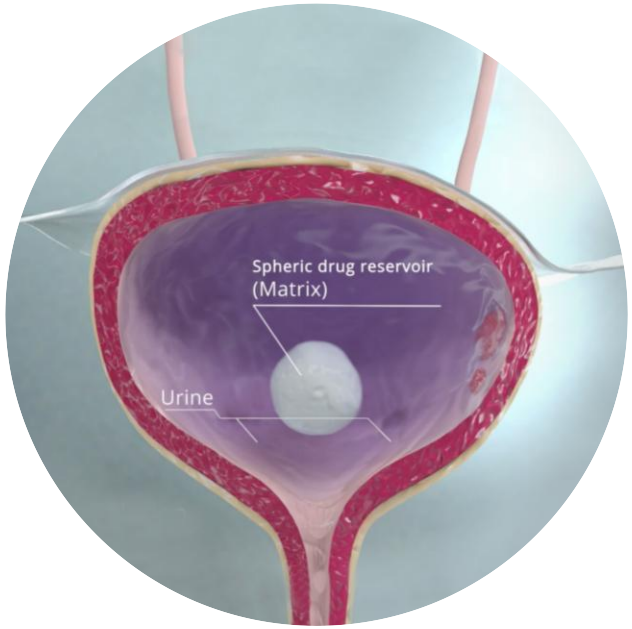
Conventional Gem/Doce Issue	NDV-01 Solution
Limited drug exposure and dwell time	vs. NDV-01 which provides **sustained release** of Gem/Doce for up to 10 days
Up to 4-hour total conventional Gem/Doce procedure time	vs. **<5 minutes** in office procedure for NDV-01
Requires specialized pharmacy preparation	vs. NDV-01 comes in prefilled syringes **ready to use** without need for specialized preparation/storage/handling
Utilization concentrated in academic setting	vs. NDV-01 which provides the opportunity for **broad utilization** of Gem/Doce across the NMIBC disease spectrum

NMIBC: Non-muscle invasive bladder cancer; **Gem/Doce**: Gemcitabine plus Docetaxel

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NDV-01: Novel Sustained-Release Intravesical Gem/Doce

How NDV-01 Works



Gel A

Hydrophilic Carbomer Gel

Instilled into an empty bladder via standard catheter. Forms a scaffold for the NDV-01 Gem/Doce matrix.

Gel B

Hydrophobic NDV-01 Matrix

Soft spherical matrix containing Gem/Doce forms within the bladder. The matrix gradually releases the chemotherapy co-formulation into the bladder for up to 10 days.

Commercial Target Product Profile



Gel A = 60 mL sterile Carbomer gel

Gel B = 15 mL sterile Gem/Doce gel

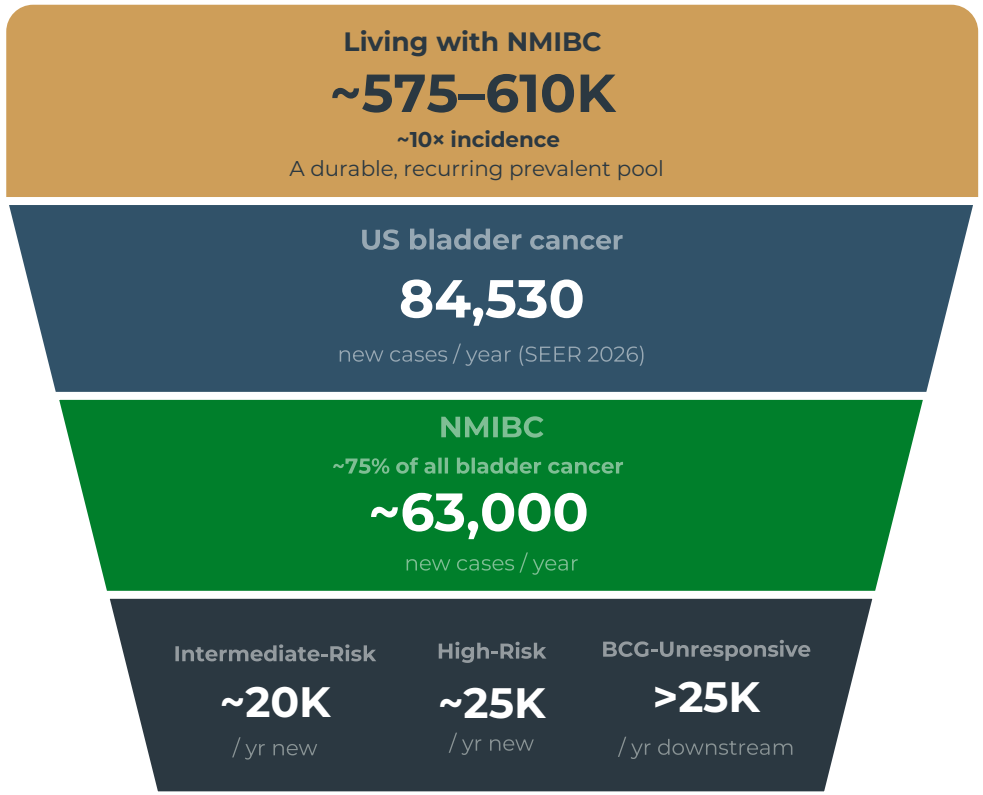
Ready to Use = no specialized preparation, storage, handling, disposal requirements

NMIBC: Non-muscle invasive bladder cancer; **Gem/Doce**: Gemcitabine plus Docetaxel

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A Large, Durable NMIBC Market – Opportunity Remains for Potential Best-in-Class Therapy

US disease burden funnel



Clinical patterns trending toward bladder-sparing therapy, increasing later-line treatment volumes

A durable, attractive market

Large and recurring

~63,000 new NMIBC patients/yr on top of a ~575–610K prevalent pool; high recurrence means patients cycle through multiple lines of therapies for years.

The opportunity is also shifting earlier

Novel agents are pushing up the disease sequence into the underserved high-risk BCG-naïve, BCG-exposed “gray zone”, and intermediate-risk disease.

Premium pricing is established

Approved novel agents already command ~$129K–$690K per patient/year, with broad payer coverage and J-codes – the category supports specialty economics.

Community-driven, office-based

~80% of NMIBC is managed in community urology – a channel that would welcome a simple, ready-to-use in-office intravesical product over complex modalities, BCG-dependent, or device- / infusion-based regimens.

Patient estimates by risk group do not reflect the 2026 guideline updates that redefine intermediate and high-risk disease for HG Ta tumors. Incidence: 84,530 new US bladder-cancer cases (SEER 2026), ~75% NMIBC (NCCN); Prevalence: 763,031 living with bladder cancer in the US (SEER 2023); NMIBC ~75–80% of that. Risk-tier figures are approximate estimates including 40% HR and 30% IR; BCG-unresponsive is a downstream failure state that includes multiple lines of treatment, not incident diagnosis and includes patients intolerant to BCG.

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Phase 2 Study for High-Risk NMIBC

An open-label, single-arm, single-center Phase 2 study (TRGC-011) to evaluate safety and efficacy of NDV-01 in HR NMIBC patients (NCT06663137)

HR: High Risk; **NMIBC:** Non-muscle invasive bladder cancer

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ONGOING TRGC-011 STUDY

Study Design



Inclusion Criteria

- High-risk NMIBC
- BCG-naive, BCG-exposed, and BCG-unresponsive patients

Primary Endpoint

- Safety
- CR Rate at anytime

Secondary Endpoints

- CR Rate at 12 months
- HG-RFS
- PK (exploratory)

Efficacy Assessment

- CR = negative cystoscopy and negative urine cytology
- Biopsy if indicated
- Assessed every 3 months

NMIBC: Non-muscle invasive bladder cancer; **CR:** Complete Response; **DOR:** Duration of Response; **HG-RFS:** High Grade – Recurrence Free Survival; **PK:** Pharmacokinetics; **BCG:** Bacillus Calmette-Guérin

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Demographic Data

Characteristics	N=51	%
Age		
Median (range)	72 (52–93) yr	
Sex		
Male	43	84.3%
Female	8	15.7%
BCG doses		
Median BCG doses (range)	12 (1–18)	
BCG-status		
BCG-naive	24	47.1%
BCG-exposed	4	7.8%
BCG-unresponsive	23	45.1%
Stage		
CIS +/- Ta/T1	16	31.4%
Ta HG	29	56.9%
T1 HG	6	11.8%

Efficacy-evaluable Cohort 1 patients (N=51): treated patients with ≥1 NDV-01 dose(s) post-baseline response assessment. Prior BCG doses among patients with prior BCG.
BCG: Bacillus Calmette-Guérin; **CIS:** Carcinoma In Situ; **Ta:** Noninvasive papillary carcinoma; **T1:** Tumor invades lamina propria**; HG:** High grade

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ONGOING TRGC-011 STUDY

Complete Response (CR) Through 12 Months

Overall Population[1] (n=51; CR)

	n/N	%
Anytime	48/51	94%
3-month	45/51	88%
6-month	38/46	83%
9-month	33/38	87%
12-month	24/31	77%

- 3 of 6 patients re-induced after a 3-month non-CR achieved CR at Month 6
- 100% Progression free survival: No patients progressed to muscle-invasive or metastatic bladder cancer through Month 12
- 100% Cystectomy free survival: No patients underwent a radical cystectomy through Month 12

BCG-UR Subpopulation[1] (n=23; CR)

	n/N	%
Anytime	22/23	96%
3-month	20/23	87%
6-month	16/21	76%
9-month	13/16	81%
12-month	11/15	73%

- 2 of 3 patients re-induced after a 3-month non-CR achieved CR at Month 6

1. Efficacy-evaluable patients (N=51): treated patients with ≥1 NDV-01 dose(s) post-baseline response assessment. Rates include CRs after re-induction; a missed assessment between two CRs is counted as CR. Data cut 12-Oct-2026; preliminary. **CR:** Complete response; **BCG:** Bacillus Calmette-Guérin; **BCG-UR**: BCG-Unresponsive.

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ONGOING TRGC-011 STUDY

Extended Durability in 12-Month Complete Responders

Overall Population LTE[1] (n=23; CR)

	n/N	%
15-month	15/18	83%
18-month	12/14	86%

- 1 patient with 12-month CR did not enter Long Term Extension (LTE)
- n = 23 patients in LTE (18 evaluable at Month 15; 14 at Month 18)
- 12 of 14 patients (86%) remained in CR at Month 18
- 2 patients progressed to muscle-invasive bladder cancer (T2a) at the Month 15 assessment:
  - 1 BCG-Naïve (T1)
  - 1 BCG-Naïve (CIS+T1)
- No patients underwent a radical cystectomy through Month 18

BCG-UR Subpopulation LTE[1] (n=11; CR)

	n/N	%
15-month	8/9	89%
18-month	7/8	88%

- n = 11 BCG-UR patients in LTE (9 evaluable at Month 15; 8 at Month 18)
- 7 of 8 patients (88%) remained in CR at Month 18

1. Patients in CR at the 12-month landmark who continued on study beyond 12 months. Data cut 12-Oct-2026; preliminary. **LTE:** Long-term extension; **CR:** Complete Response; **BCG-UR:** BCG-unresponsive.

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ONGOING TRGC-011 STUDY

Treatment-Related AEs and Tolerability

- **35 of 51 patients (69%) had a TRAE**
  - 55% transient uncomfortable urination (dysuria)
  - 22% hematuria
  - 16% urinary urgency / frequency
- **No ≥ Grade 3 TRAEs and no treatment-related SAEs**
- **No patients discontinued due to TRAEs**

TRAE: Treatment-related (related or possibly related) adverse event; **AE:** Adverse event; **SAE:** Serious adverse event. Cohort 1 efficacy-evaluable patients (N=51); preliminary.

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SPECTRUM

NDV-01 Phase 3 Program

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SPECTRUM Phase 3 Program Built on Two Independent FDA Registrational Pathways

Registrational cohorts

Each designed to independently support potential FDA regulatory approvals

2UC N=87

High Risk Second-line (2L) BCG-Unresponsive CIS ± Ta/T1

Single arm

IRA N=276 (under review)

Intermediate Risk Adjuvant *versus* Observation

Randomized 1:1

Planned exploratory cohort

Evidence generation; not for registration

2UP N=50

2L HR BCG-UR Ta/T1 w/o CIS (papillary only)

Single arm

NMIBC: non-muscle invasive bladder cancer; **BCG:** Bacillus Calmette-Guérin; **BCG-UR:** BCG-unresponsive; **CIS:** carcinoma in situ; **HR:** high risk; **IR:** intermediate risk; **1L:** first-line; **2L:** second-line

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PHASE 3 SPECTRUM TRIAL

Cohorts 2UC/2UP: 2L BCG-Unresponsive NMIBC

Registrational open-label, single-arm trial



Inclusion Criteria

- HR BCG-UR NMIBC with CIS ± Ta/T1
- Failed one or two lines of 1L BCG-UR therapy

Primary Endpoint

- CR rate at anytime (2UC)
- HG-RFS (2UP)
- Safety

Key Secondary Endpoints

- 12-Month DOR
- PFS
- HG-RFS
- CFS
- QOL
- PK (exploratory)

Efficacy Assessment

- CR = negative cystoscopy and negative urine cytology
- Biopsy if indicated
- Assessed every 3 months

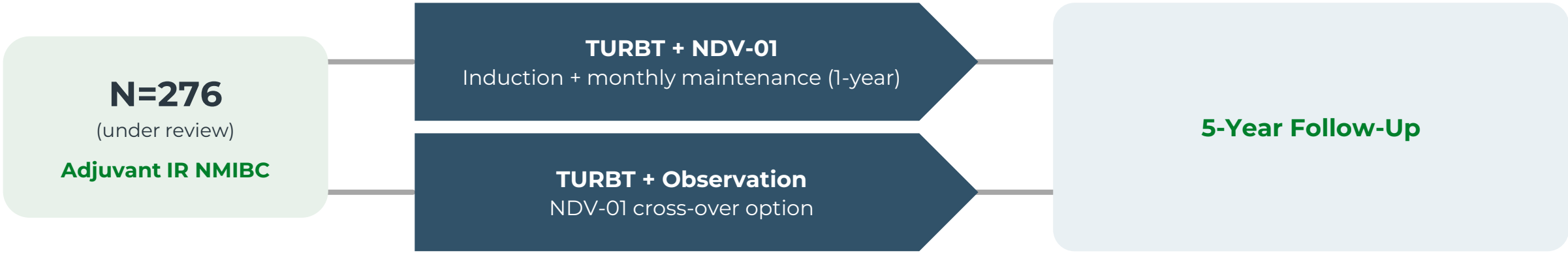
1. BCG-Unresponsive patients with CIS +/- Ta/T1 disease; Phase 3 Cohort 2UC is a registrational cohort intended for regulatory approval. **2.** BCG-Unresponsive patients with high-grade Ta/T1 disease. Cohort 2UP is an exploratory cohort and not intended for regulatory approval. **NMIBC:** Non-muscle invasive bladder cancer; **BCG:** Bacillus Calmette-Guérin; **2L:** Second Line Registrational cohort designed to support potential FDA approval. **CIS:** carcinoma in situ; **HR:** high risk; **BCG-UR:** BCG-unresponsive; **CR:** complete response; **DOR:** duration of response; **PFS:** progression-free survival; **RFS:** recurrence-free survival; **PK:** pharmacokinetics.

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PHASE 3 SPECTRUM TRIAL

Cohort IRA: Adjuvant Intermediate-Risk NMIBC

Registrational Randomized (1:1) Trial – TURBT + NDV-01 vs. TURBT + Observation



Inclusion Criteria

- IR NMIBC (no high-grade)
- ≥1 IBCG risk factor
- TURBT within 12 weeks (± single-dose peri-operative chemotherapy)

Primary Endpoint

- DFS*
- Safety

Key Secondary Endpoints

- HG-RFS
- PFS
- QOL

Stratification

- 1-2 vs 3+ IBCG risk factors
- Single-dose peri-operative chemotherapy (yes vs. no)

*DFS = time from randomization to the first documented recurrence or progression. Sample size under review. **DFS:** disease-free survival; **HG-RFS:** high-grade recurrence-free survival; **IBCG:** International Bladder Cancer Group; **IR:** intermediate risk; **PFS:** progression-free survival; **QOL:** quality of life; **TURBT:** transurethral resection of bladder tumor

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PHASE 3 SPECTRUM TRIAL

On Track to Submit NDV-01 IND by Year-End 2026 and Initiate Phase 3 SPECTRUM Upon IND Clearance

YE26

NDV-01 United States IND Submission

Upon IND Clearance

Initiate Phase 3 SPECTRUM Program

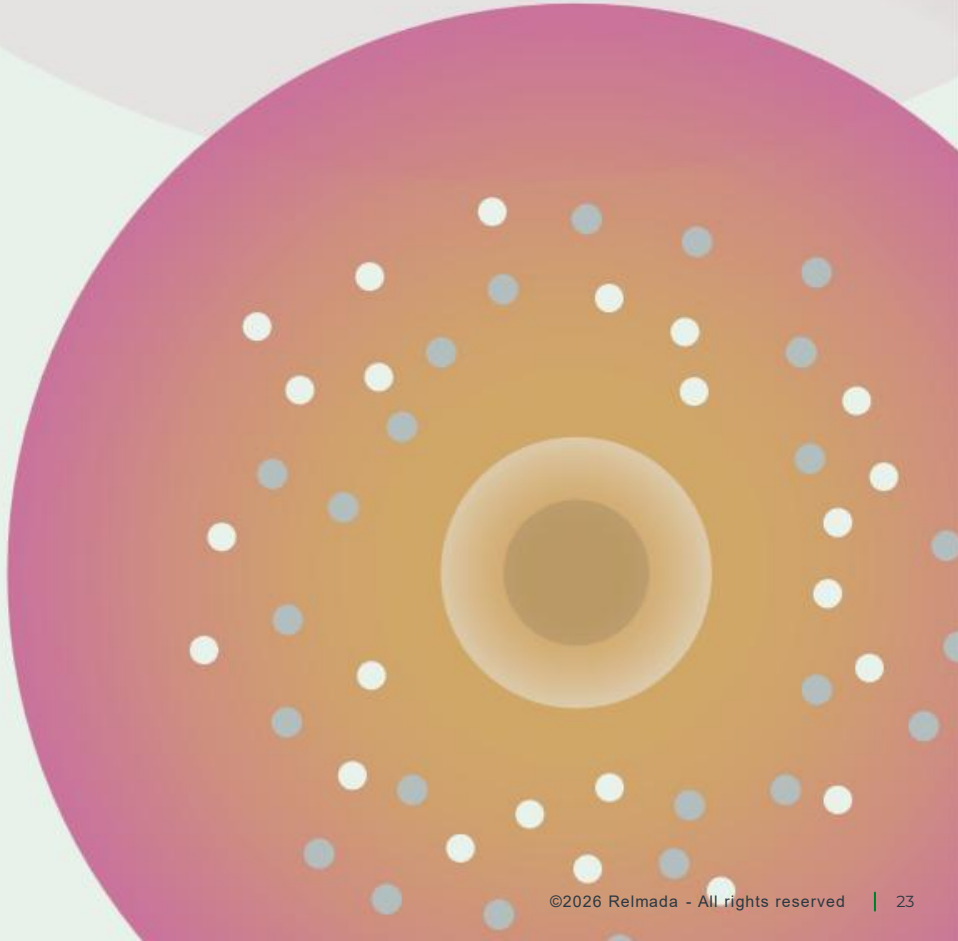
Two independent registrational pathways:

- 2L BCG-Unresponsive NMIBC patients
- Adjuvant Intermediate-Risk NMIBC patients

BCG: Bacillus Calmette-Guérin (BCG); **NMIBC:** Non-muscle invasive bladder cancer;

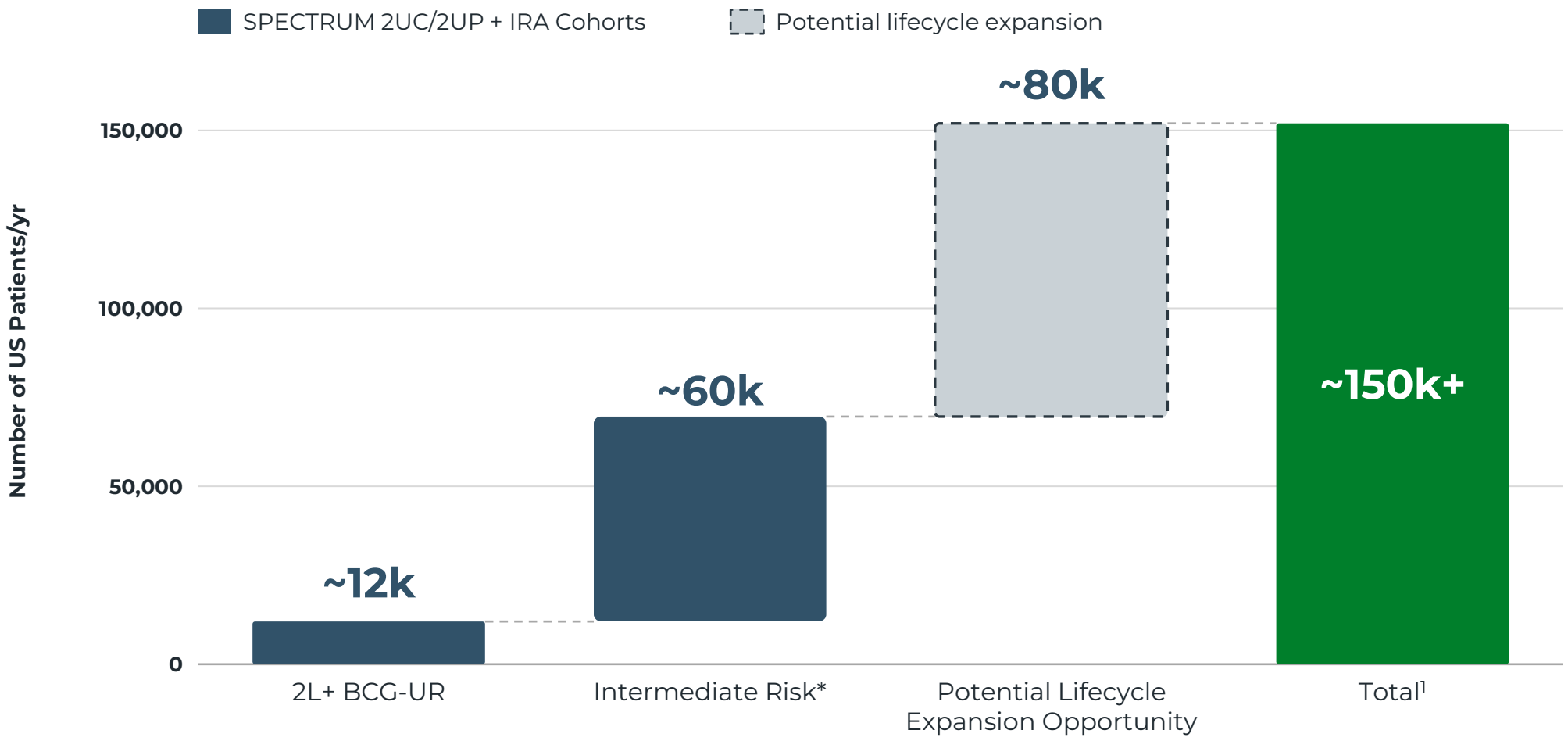
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NDV-01 Market Opportunity



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SPECTRUM Registrational + Potential Lifecycle Expansion Opportunity

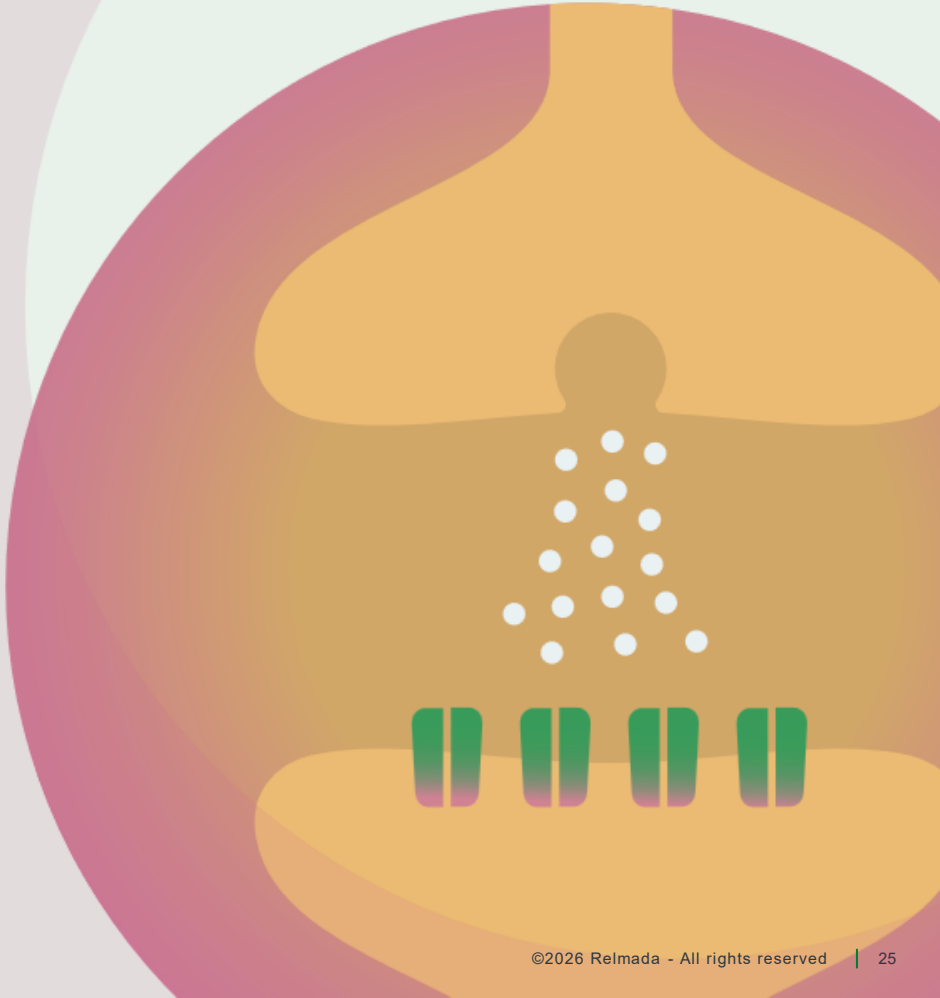


1. Based on Internal estimates.* Includes recurrent patients.

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Sepranolone

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



GAMSA: a GABA-A modulating steroid antagonist. The graphic is for artistic purposes only, not a factual representation

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Sepranolone Has the Potential to Normalize $GABA_A$ Receptor Activity

GABA (ϒ-aminobutyric acid) is the primary neurotransmitter, involved in anxiety and compulsive disorders[1,2]

Allopregnanolone (ALLO) typically enhances $GABA_A$ calming effects[3, 4]

In some individuals, ALLO exacerbates anxiety and compulsivity[5, 6]

Sepranolone normalizes $GABA_A$ receptor activity without interfering in GABA signaling[7,8]

1. Nuss P et al. Neuropsychiatr Dis Treat. 2015. **2.** Möhler H. Neuropharmacology. 2012. **3.** Belelli D et al. Nat Rev Neurosci. 2005. **4.** Majewska MD et al. Science. 1986. **5.** Girdler SS et al. Biol Psychiatry. 2001. **6.** Bixo M et al. Br J Psychiatry. 2025. **7.** Bixo M et al. Psychoneuroendocrinology. 2017. **8.** Bäckström T et al. Psychoneuroendocrinology. 2021. **$GABA_A$:** ϒ-aminobutyric acid type A; **ALLO:** Allopregnanolone

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Sepranolone: Highlights & Development Value

- **Differentiated therapeutic candidate** for compulsivity-related disorders, supported by positive proof-of-concept data in Tourette's syndrome
- **Phase 2b study in Prader-Willi syndrome (PWS)** – a rare genetic disorder affecting 350,000–400,000 individuals worldwide – planned pending IND clearance
- **Program readiness:** Regulatory engagement and manufacturing operations are actively underway, supporting efficient trial initiation
- **Orphan/rare disease incentives:** Potential for orphan drug designation, including regulatory exclusivity, accelerated approval pathways, and enhanced commercial positioning
- **Strategic investor value:** Clear development milestones, potential for first-in-class differentiation, and meaningful opportunity in a high-unmet-need rare disease

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On Track to Submit Sepranolone IND by Year-End 2026 and Initiate Phase 2b Trial in PWS Upon IND Clearance

YE26

Sepranolone United States IND Submission

Upon IND Clearance

Initiation of Phase 2b study in Prader-Willi Syndrome

Focus on evaluating early proof-of-concept

PWS: Prader-Willi syndrome

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Corporate Summary

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Financial Overview

$202.1 million[1]

Cash, cash equivalents & short-term investments

As of September 30, 2026

~106.7 million[1]

Common shares outstanding

~127.9M as converted – includes ~14.9M outstanding options (weighted average exercise price of $12.58/share) and ~6.3M outstanding warrants

1. As of September 30, 2026;

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Thank You!