Relmada THERAPEUTICS

CORPORATE OVERVIEW

Unlocking Life Changing Therapies

September 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.

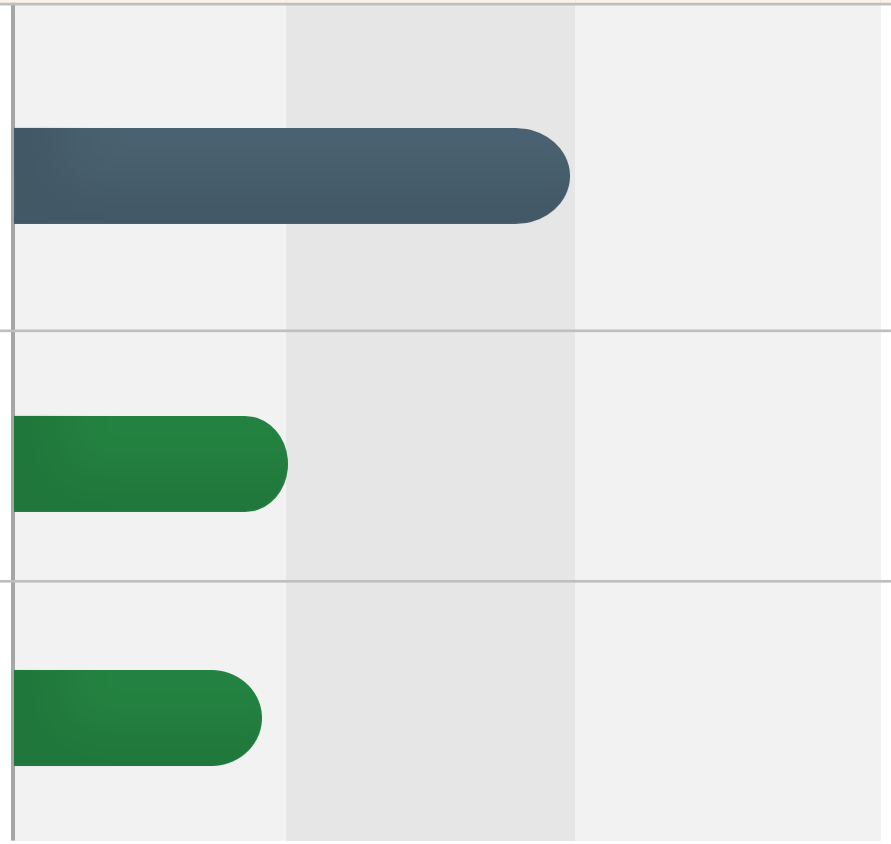
These statements are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including potential for Phase 2 NDV-01 data to continue 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.

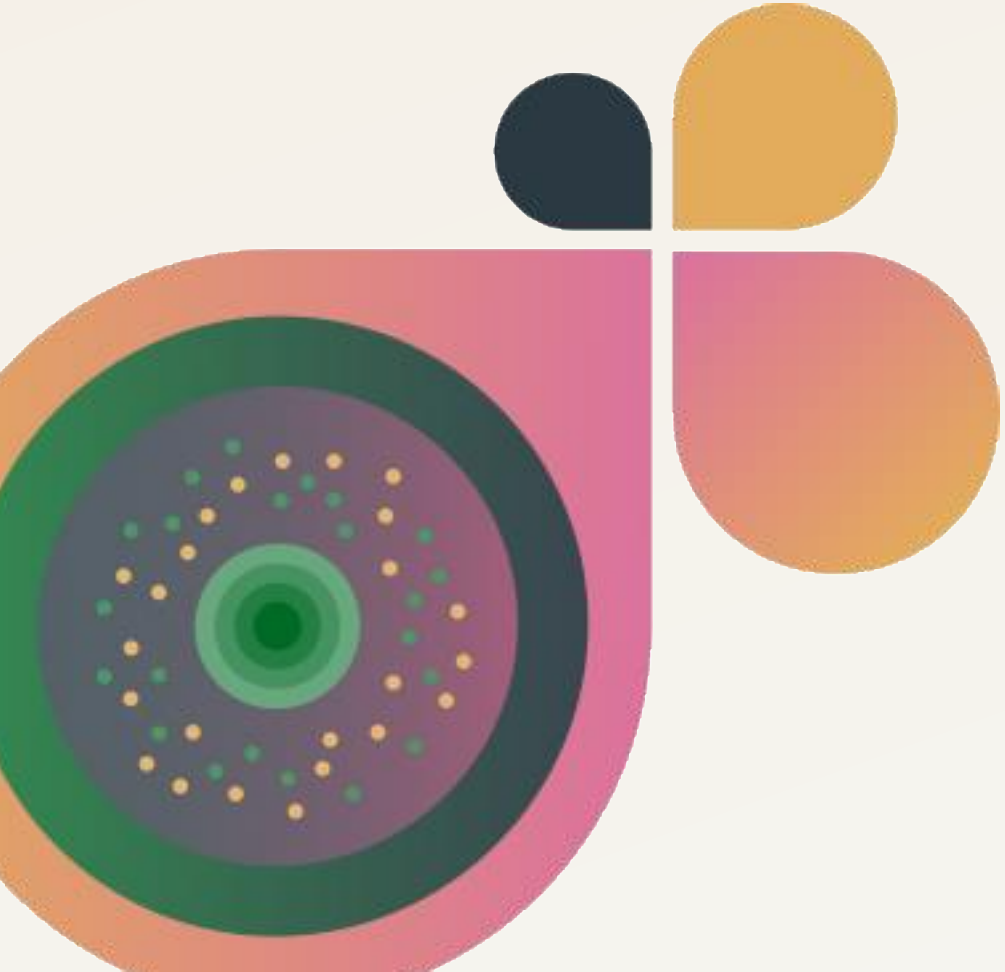
Innovative pipeline of potential high-value assets

Focused on programs with positive proof-of-concept data

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



1. NDV-01: A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce); **2.** Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment"); **3.** Markets, Research And. "Non-muscle Invasive Bladder Cancer (NMIBC) Epidemiology Forecasts to 2034." *GlobeNewswire News Room*, 25 Jan. 2024; **4.** 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[1]

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

Our focus: non-muscle invasive bladder cancer (NMIBC)

High incidence[1]

4.2% of all new cancer cases in the US

Strong recurrence[2,3]

~15%-61% of high-risk patients recur within one year

High-risk population[4]

74% of patients >65 y/o
73 y/o median age

High cost

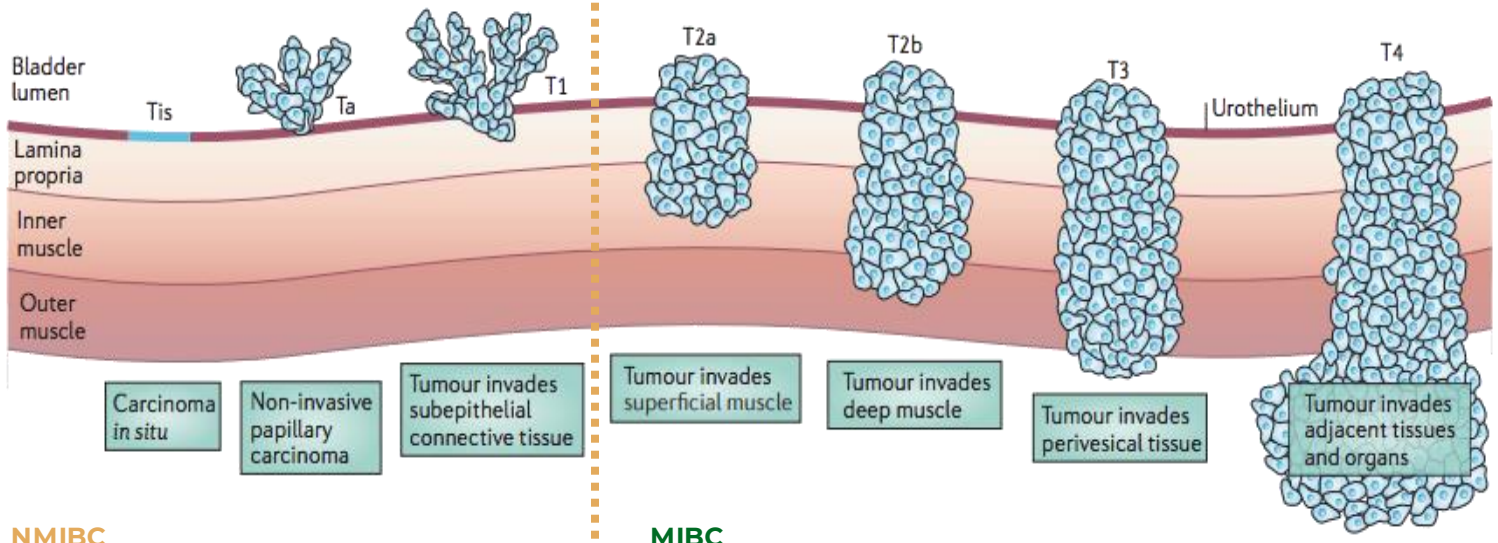
Complex treatment pathways
$6.5B total annual cost (U.S.)[5]

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

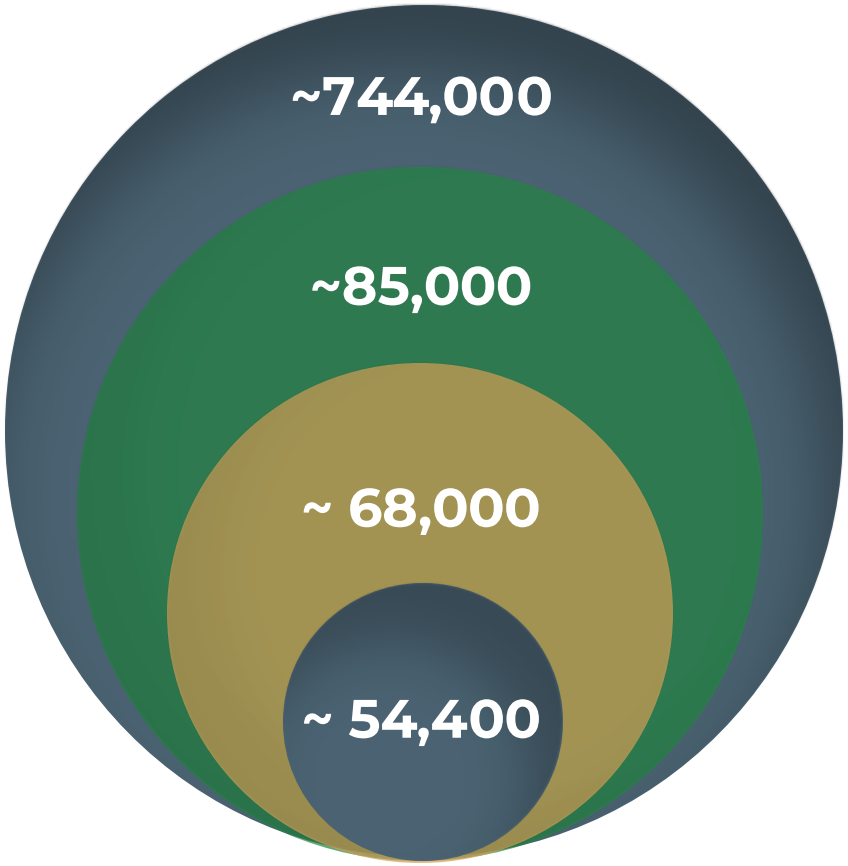
MIBC

- 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

1. SEER Cancer Stat Facts: Bladder Cancer. National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/statfacts/html/urinb.html ; **2.** Białek, Łukasz. "EORTC Bladder Cancer Recurrence and Progression Calculator." Omni Calculator, 1 Aug. 2024, www.omnicalculator.com/health/eortc-bladder-cancer; **3.** Ma J, Roumiguie M, Hayashi T, Kohada Y, Zlotta AR, Lévy S, Matsumoto T, Sano T, Black PC. Long-term Recurrence Rates of Low-risk Non-muscle-invasive Bladder Cancer-How Long Is Cystoscopic Surveillance Necessary? Eur Urol Focus. 2024 Jan;10(1):189-196. ; **4.** CG ONCOLOGY, INC. (2025, April 23). NMIBC | MIBC | Mechanism of Action of CG0070 | CG Oncology. CG Oncology |. https://cgoncology.com/science/#:~:text=4.patients%20with%20newly%20diagnosed%20disease.; **5.** enGene. (2025, September). Corporate Presentation September 2025 [Slide show]. https://www.sec.gov/Archives/edgar/data/1980845/000095017025112674/engn-ex99_1.pdf ; **6.** NASS Database Documentation. (n.d.). https://www.hcup-us.ahrq.gov/db/nation/nass/nassdbdocumentation.jsp

NMIBC opportunity

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



US prevalence of Bladder Cancer[1]
(Overall Bladder Cancer)

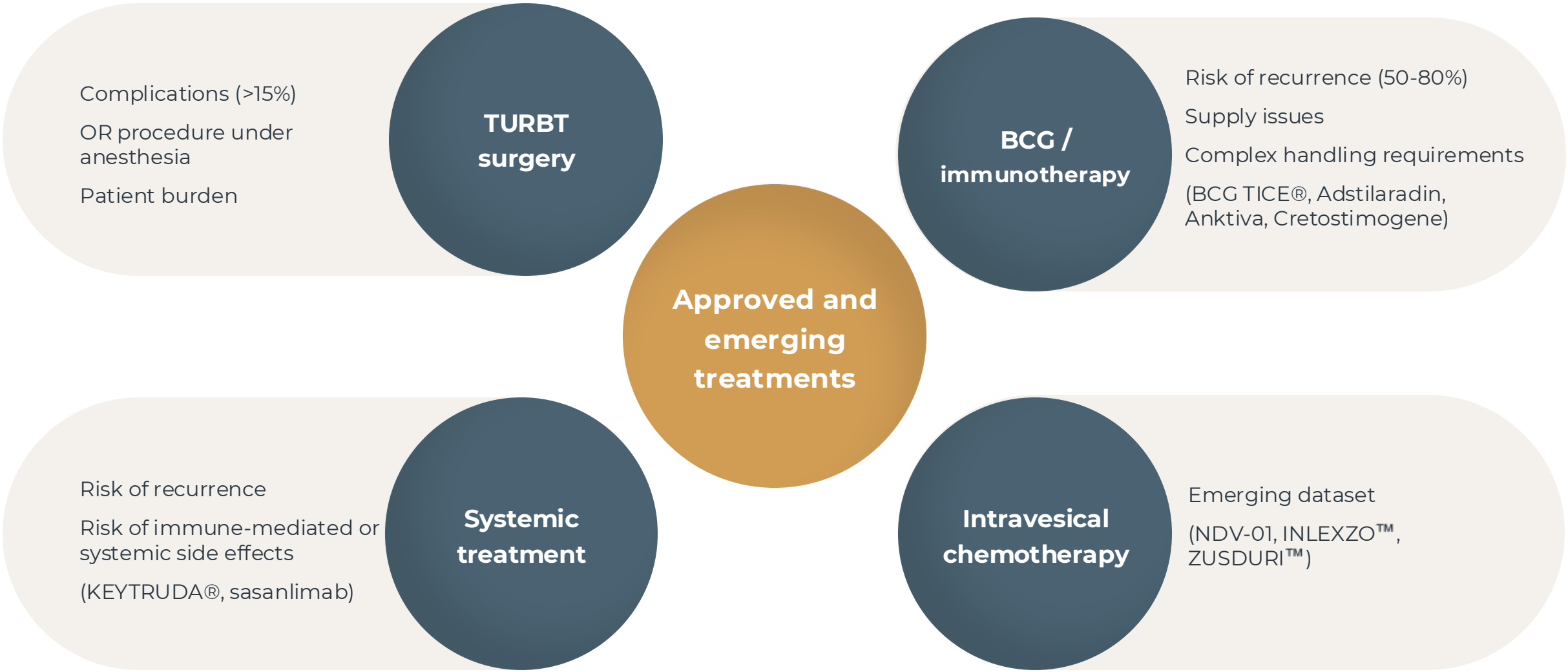
New bladder cancer cases[2]
70-96% 5-year overall survival, 6% with advanced disease[3]

NMIBC cancer cases (75-80% of bladder cancers)[4, 6]
50-80% recurrence rate (over five years)[5]

Intermediate-risk and high-risk have increased risk of recurrence and progression (Intermediate-risk represents 45%[6, 7] and high-risk represents 35%[7] of NMIBC cases)

1. https://seer.cancer.gov/statfacts/html/urinb.html; **2.** 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; **3.** American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025; **4.** Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment"); **5.** Białek, Łukasz. "EORTC Bladder Cancer Recurrence and Progression Calculator." Omni Calculator, 1 Aug. 2024, www.omnicalculator.com/health/eortc-bladder-cancer; **6.** 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; **7.** 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

Overview of NMIBC treatment landscape



Relmada internal market research, 2025. **NMIBC**: Non-muscle-Invasive Bladder Cancer; **TURBT:** Transurethral resection of bladder tumor; **BCG:** Bacillus Calmette-Guérin

NMIBC patient care journey

1. Urologists 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 adjunctive treatment
4. Regular cystoscopies and urine cytology (up to every 3 months) are used to monitor patients and assess for recurrence
5. For patients with recurrent disease, repeat TURBT +/- alternative intravesical treatments are used, including chemotherapies such as Gem/Doce

Based on AUA/SUO Practice Guidelines, 2024 (Event April 28, 2025 (Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment").
HR: High Risk; **NMIBC:** Non-Muscle Invasive Bladder; **BCG:** Bacillus Calmette Guérin; **TURBT:** Trans Urethral Resection of Bladder Tumor; **Gem/Doce**: Gemcitabine plus Docetaxel

The burden of recurrences and TURBT is high

Frequent recurrences for IR NMIBC patients[1]: ~ 1 recurrence / year[1]

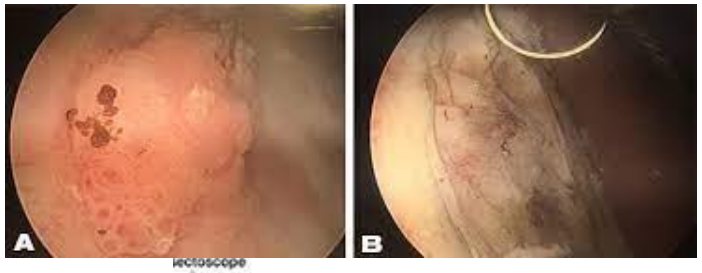
- 5-year risk of initial recurrence: 54.4%. After initial recurrence 60.1% of patients had a second recurrence by 2 years
- After 2nd recurrence, 51.5% of patients had a 3rd recurrence by 3 years[1]

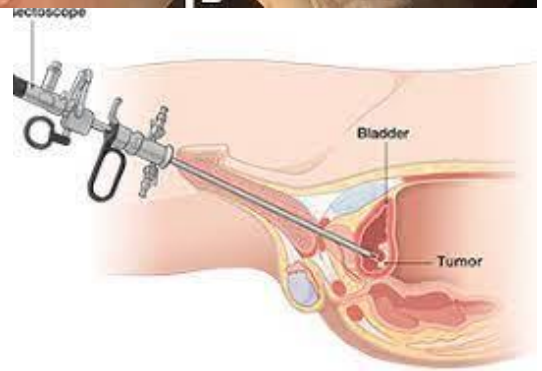
Increased risk of progression with more recurrences[1]

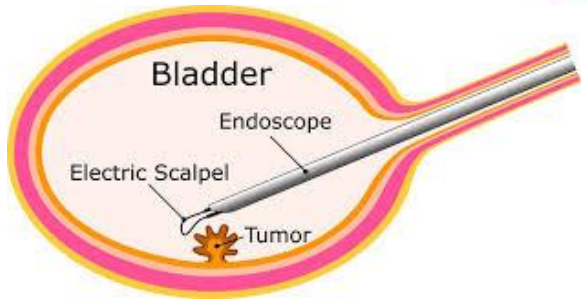
- The 5-year risk of progression: 9.5%, 21.9%, and 37.9% for patients with 1, 2, and 3+ recurrences, respectively

Recurrences typically require TURBT Invasive OR procedure with anesthesia

- Complication rate = > 15%[2]
- Grade 3/4 complication rate = 9.4%[3]
- Readmission rate = 5%[4]
- Procedural Cost = $8,000-$10,000[5]
- Worsening mental health, physical health and lower urinary tract symptom scores[6]



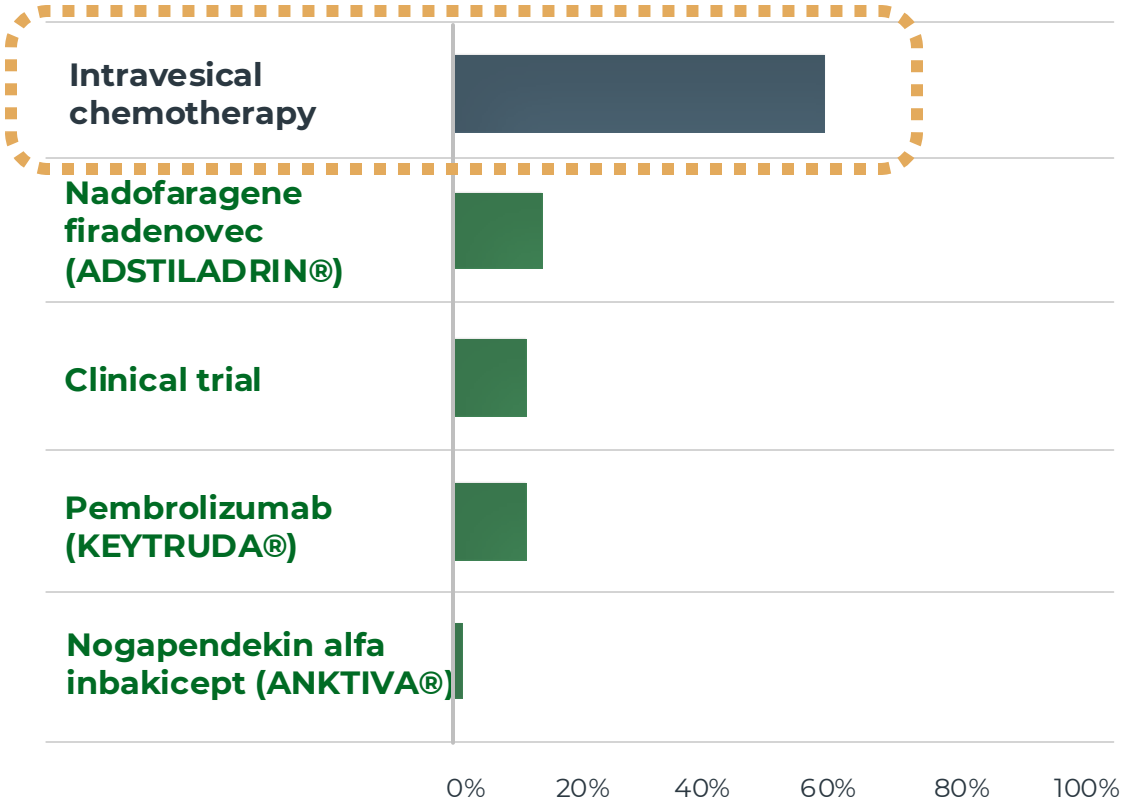




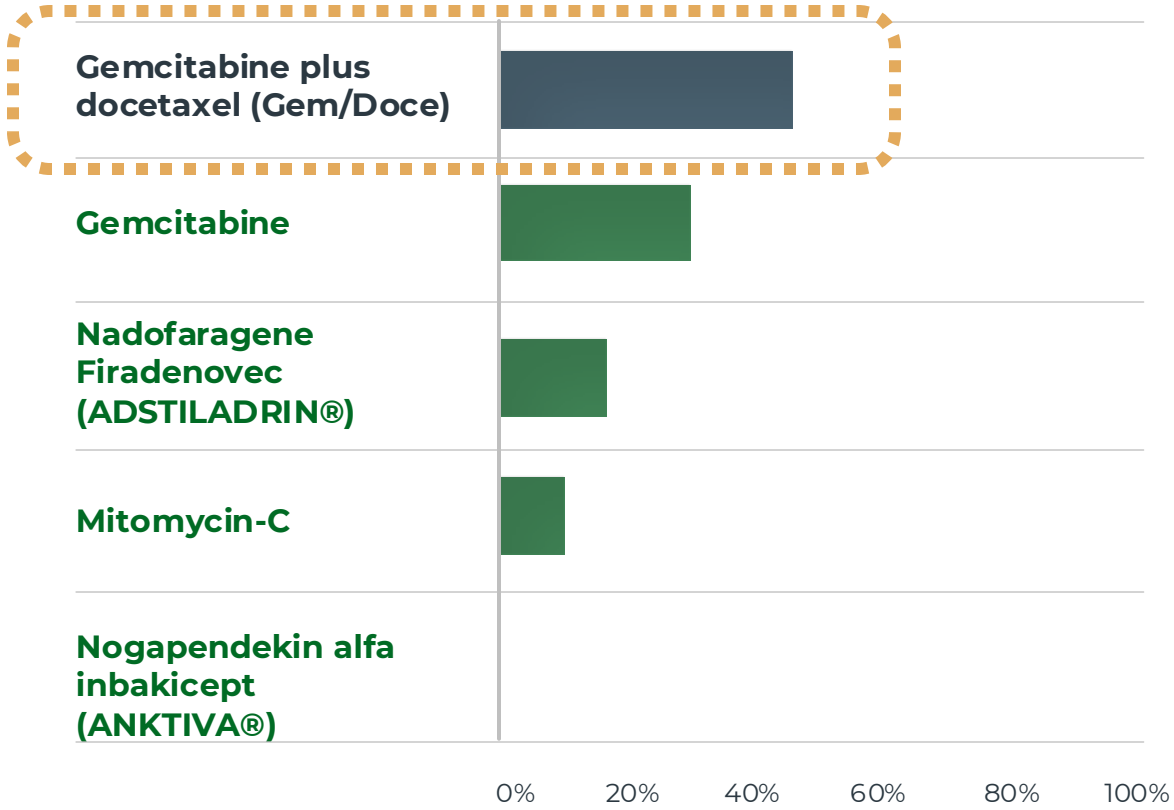
1. Sharma, V., Chamie, K., Schoenberg, M., Lee, V. S., Fero, K., Lec, P., Munneke, J. R., Aaronson, D. S., Kushi, L. H., Quesenberry, C. P., Tang, L., & Kwan, M. L. (2022). Natural history of multiple recurrences in Intermediate-Risk Non-Muscle Invasive Bladder Cancer: Lessons from a prospective cohort. Urology, 173, 134–141. https://doi.org/10.1016/j.urology.2022.12.009 ; **2.** Pattou, M., Ochoa, A., Goujon, A., Verine, J., Meyer, F., Bebane, S., Gaudez, F., Meria, P., Desgrandchamps, F., Mongiat-Artus, P., & Masson-Lecomte, A. (2025). Outpatient Transurethral Resections of Bladder Tumours: Insights from the Largest Cohort to Date. Urologia Internationalis, 1–13. https://doi.org/10.1159/000543979 ; **3.** Bansal, A., Sankhwar, S., Goel, A., Kumar, M., Purkait, B., & Aeron, R. (2016). Grading of complications of transurethral resection of bladder tumor using Clavien–Dindo classification system. Indian Journal of Urology, 32(3), 232. https://doi.org/10.4103/0970-1591.185104 ; **4.** Jindal, T., Sarwal, A., Jain, P., Koju, R., & Mukherjee, S. (2022). A retrospective analysis of the factors associated with increased risk of readmission within 30 days after primary transurethral resection of bladder tumor. Current Urology, 17(4), 257–261. https://doi.org/10.1097/cu9.0000000000000160 ; **5.** MediGence. (n.d.). Trans Urethral Resection of Bladder Tumor (TURBT) cost worldwide - Compare prices. https://medigence.com/hospitals/urology/trans-urethral-resection-of-bladder-tumor...**5.** Lee LJ, et al.. Humanistic and Economic Burden of Non-Muscle Invasive Bladder Cancer: Results of Two Systematic Literature Reviews. Clinicoecon Outcomes Res. 2020 Nov 23;12:693-709.

Gem/Doce combination stands out in *Urology Times* survey[1]

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?



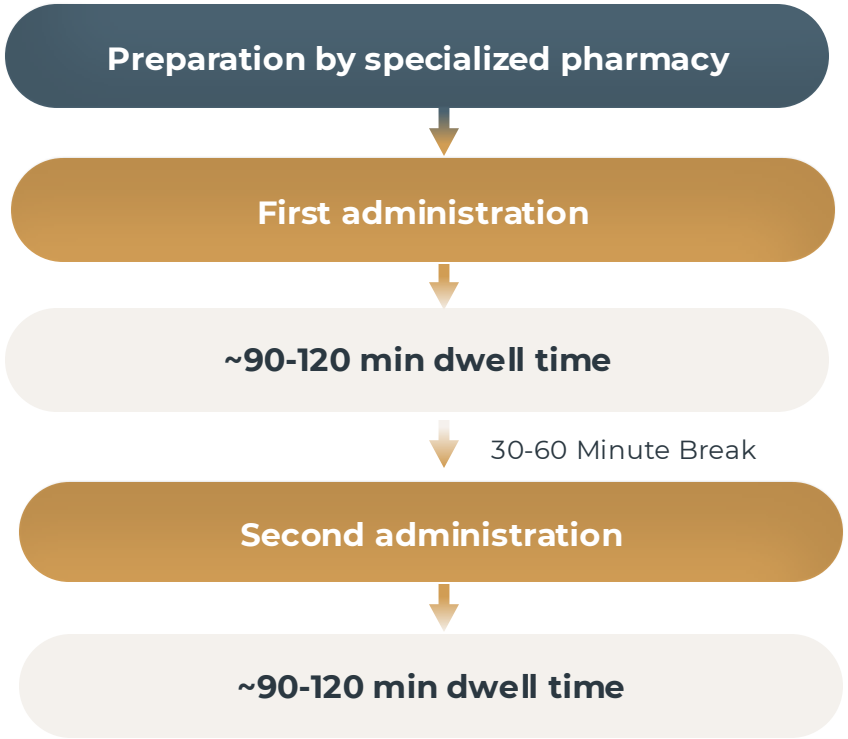
1. Derived from Urology Times: Survey on Treatment Patterns and Preferences in Non–Muscle Invasive Bladder Cancer, June 2025, based on responses from 42 practicing physicians (Saylor, Benjamin P. "Survey: New NMIBC Treatments Face Slow Uptake." *Urology Times*, 17 July 2025, www.urologytimes.com/view/survey-new-nmibc-treatments-face-slow-uptake.)

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%[1, 2, 3]
- Gem/Doce is an effective alternative first-line agent in **high-risk BCG naïve** patients with 2-year RFS of 82%[4]
- Gem/Doce use expanding into **intermediate-risk and low-grade tumors** with reported 2-year RFS of 70-80%[5, 6]
- Gem/Doce **avoids/delays radical cystectomy**[7, 8]
- 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**: Gemcitabine plus Docetaxel

Conventional Gem/Doce intravesical therapy for NMIBC



4-hour total procedure time

~ 5 minutes for NDV-01

Requires specialized pharmacy preparation

NDV-01 comes ready for use in pre-filled plastic syringes

Complication rates for Conventional Intravesical Therapy

BCG[1,2,6]

cystitis, urinary frequency < 1/hr (24%-82%), hematuria (23-74%), dysuria (50-70%), bladder contracture, bladder ulcerations, systemic infection

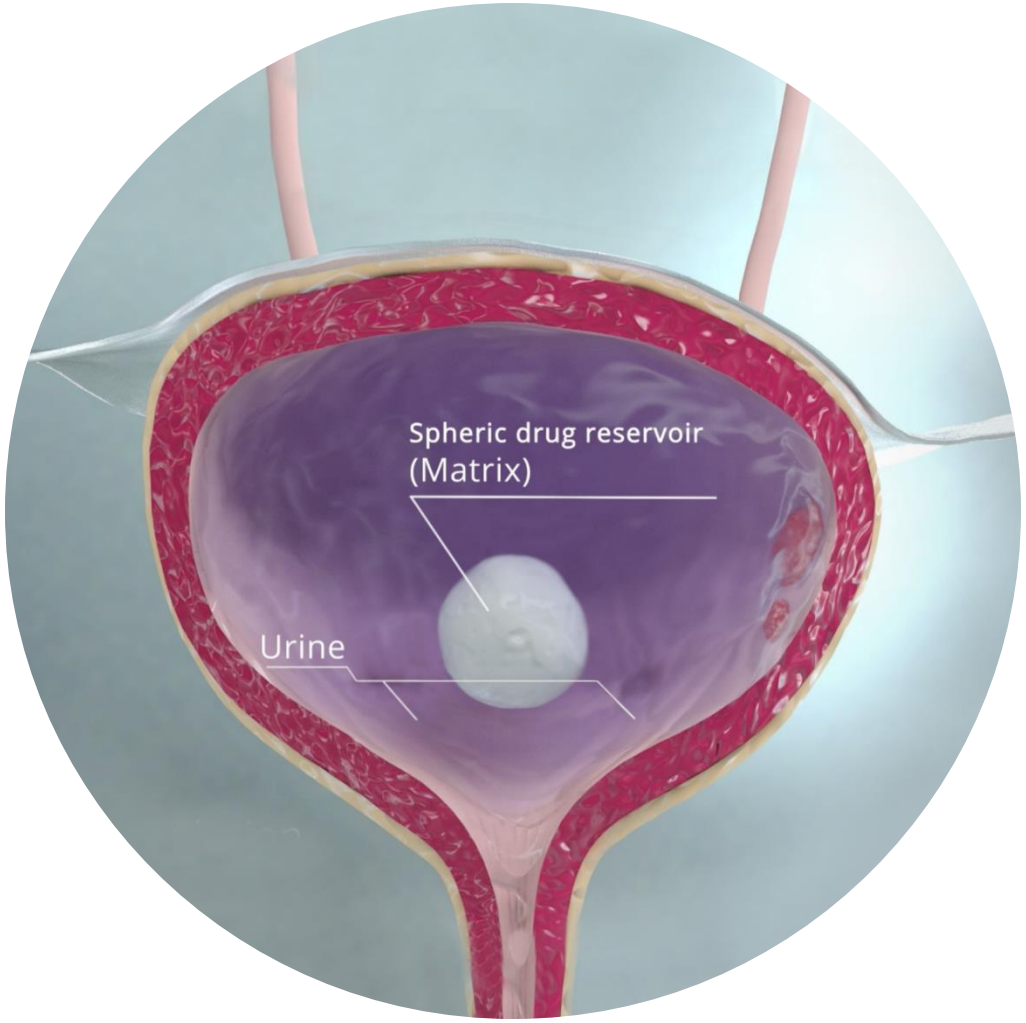
~7–20% of patients are forced to discontinue BCG therapy due to the severity of their lower urinary tract symptoms (LUTS)

MMC/Gemcitabine[3,4,5]

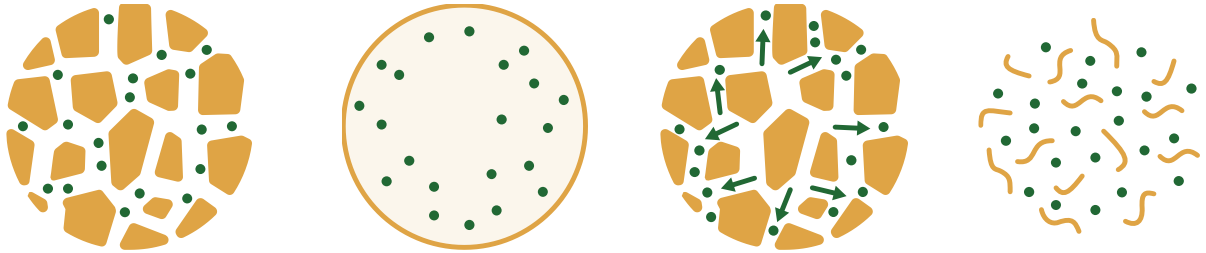
Hematuria (24%), frequency (22%), chemical cystitis (7%)

1. U.S. Food and Drug Administration & Center For Biologics Evaluation And Research. (2018, February 21). TICE BCG. U.S. Food And Drug Administration. https://www.fda.gov/vaccines-blood-biologics/vaccines/tice-bcg ; **2.** Liu, Y., Lu, J., Huang, Y., & Ma, L. (2019). Clinical spectrum of complications induced by intravesical immunotherapy of bacillus Calmette-Guérin for bladder cancer. Journal of Oncology, 2019, 1–11. https://doi.org/10.1155/2019/6230409 ; **3.** UroGen Pharma. (2025). HIGHLIGHTS OF PRESCRIBING INFORMATION [Press release]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215793s000lbl.pdf ; **4.** Janssen Biotech, Inc. (2025). HIGHLIGHTS OF PRESCRIBING INFORMATION [Press release]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219683s000lbl.pdf ; **5.** Li, R., Li, Y., Song, J., Gao, K., Chen, K., Yang, X., Ding, Y., Ma, X., Wang, Y., Li, W., Wang, Y., Wang, Z., & Dong, Z. (n.d.). Intravesical gemcitabine versus mitomycin for non-muscle invasive bladder cancer: A systematic review and meta-analysis of randomized controlled trial. BMC Urology. https://doi.org/10.1186/s12894-020-00610-9 ; **6.** Bourlotos, G., Baigent, W., Hong, M., Plagakis, S., & Grundy, L. (2024). BCG induced lower urinary tract symptoms during treatment for NMIBC—Mechanisms and management strategies. Frontiers in Neuroscience, 17. https://doi.org/10.3389/fnins.2023.1327053 ; **NMIBC**: Non-Muscle Invasive Bladder; **BCG:** Bacillus Calmette Guérin; **LUTS:** Lower Urinary Tract Symptoms; **MMC:** Mitomycin-C; **HRQoL:** Health-Related Quality of Life; **Gem/Doce**: Gemcitabine plus Docetaxel

Targeted intravesical therapy



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



Diffusion through pores

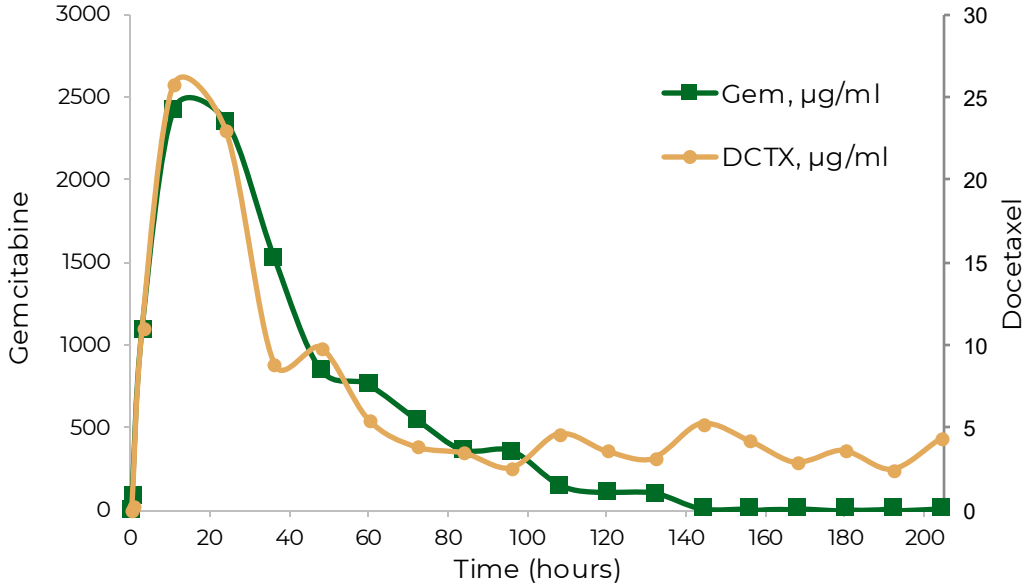
Diffusion through the polymer

Osmotic pumping

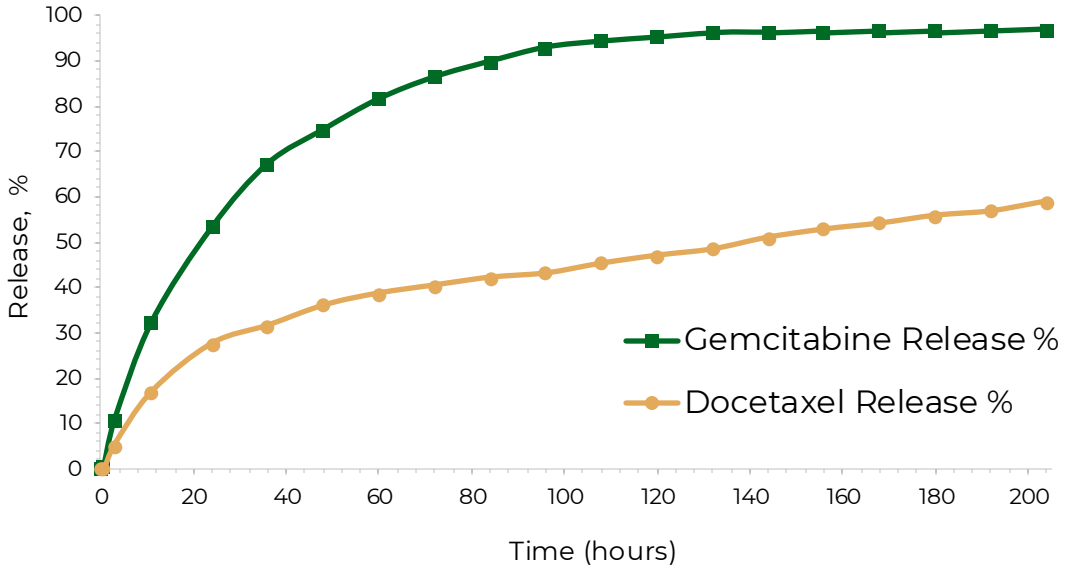
Erosion

NDV-01 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 370C, 20 rpm. The AUF sample was withdrawn twice a day and replaced by fresh AUF. The drugs concertation in the UAF was quantitatively determined by HPLC

NDV-01 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 manually in **< 5 minutes**

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

Convenience

Patient is treated **in doctors' office**

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

Relmada internal market research 2025. **NMIBC:** Non-muscle-Invasive Bladder Cancer; **Gem/Doce**: Gemcitabine plus Docetaxel

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)

American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025. **HR:** High Risk; **NMIBC:** Non muscle invasive bladder cancer

ONGOING TRCG-011 STUDY

Study design

Inclusion criteria

- High-risk disease with CIS/Tis, Ta, T 1 tumors[1, 2]
- 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

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

ONGOING TRCG-011 STUDY

Efficacy and tolerability

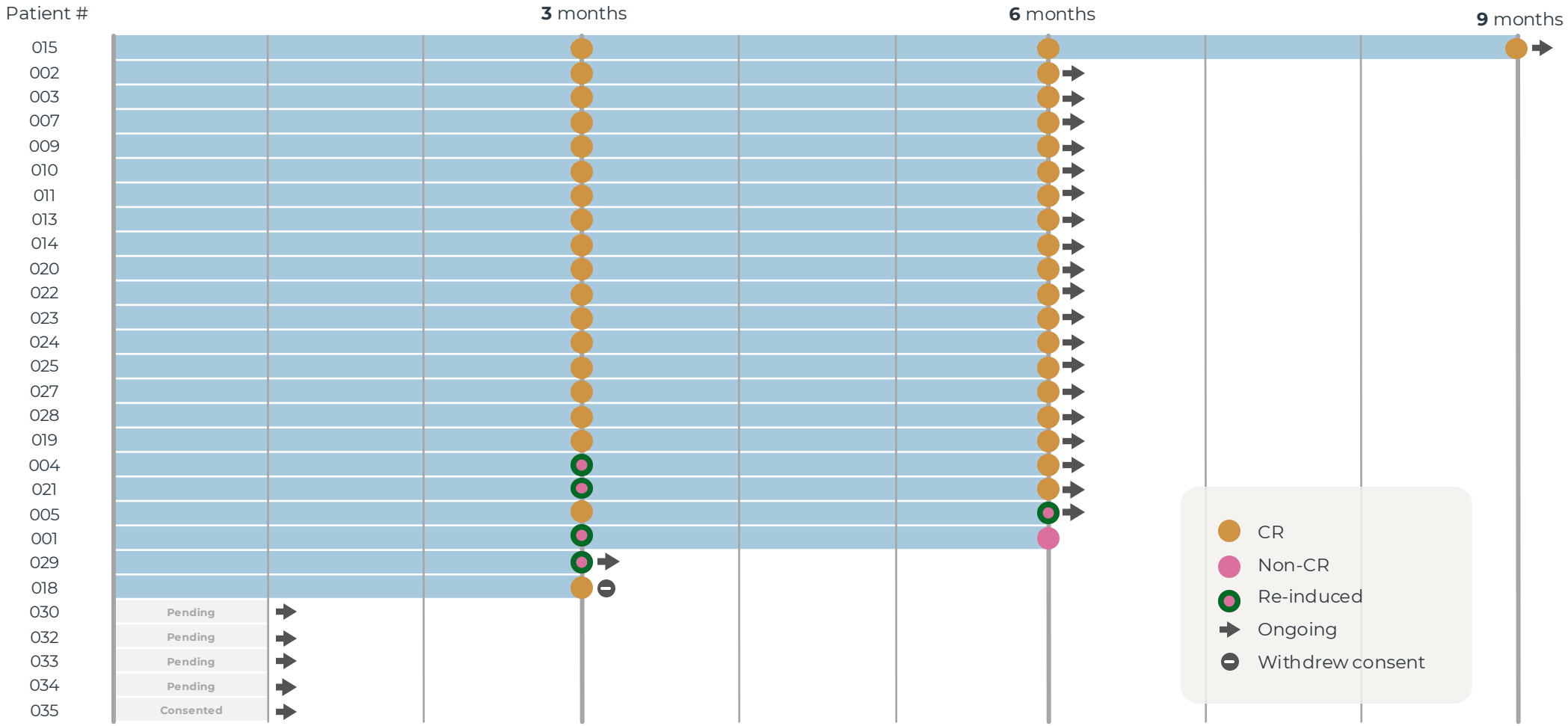
Complete response	n/N	%
Anytime	21/23	91%
3-month	19/23	83%
6-month	19/21[1]	90%

- One subject has reached the 9-month assessment and had a Complete Response
- No patient had progression to muscle-invasive disease
- No patient underwent a radical cystectomy
- No patient had >= Grade 3 TRAE
- No patients discontinued treatment due to AEs

1. 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)

ONGOING TRCG-011 STUDY

Demonstrated durable response over time



91%
Anytime CR rate

83%
3-month CR rate

90%
6-month CR rate

Pending completion

CR: Complete response

NDV-01 compared

Product / product profile	NDV-01	INLEXZO™	ZUSDURI™
Sponsor	Relmada	Johnson & Johnson	UroGen
Active Agent	Gemcitabine/docetaxel (Gem/Doce)	Gemcitabine	Mitomycin C
NMIBC subtype	High-risk or intermediate-risk	High Risk	Low grade, intermediate risk
Phase	Phase 2	FDA approved	FDA approved
Dosing Format	Sustained-release hydrogel	Indwelling silicone delivery system	Reverse-thermal hydrogel
Presentation	Pre-filled syringe ready for intravesical delivery	Catheter-based insertion; cystoscopic removal	In-office dosing kit requires in-office reconstitution under chilled conditions
Requires device removal?	No	Yes, via cystoscope[1]	No
Yearly costs	NA	$690,000	$120,000

American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025. **1.** "TAR-200 - General Overview." *J&J Medical Connect*, 21 July 2025, www.jnjmedicalconnect.com/products/tar-200/medical-content/tar-200-general-overview. **NMIBC:** Non-muscle-Invasive Bladder Cancer

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

Q4 2025

Phase 2 data update
Results from 9-month follow-up

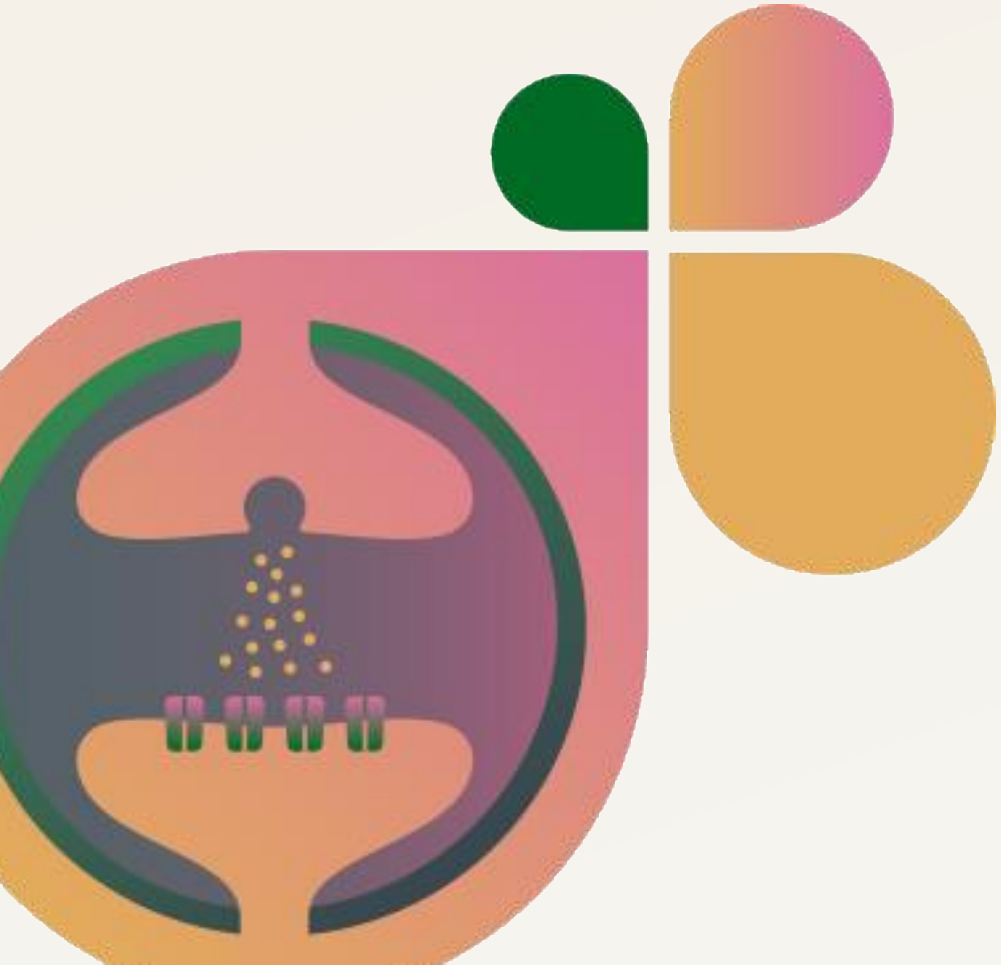
FDA engagement
Including planned FDA interactions and manufacturing

Q1 2026

Phase 2 data update
Results from 12-month follow-up

H1 2026

Initiate Phase 3 (Registrational) 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

Sepranolone has the potential to normalize $GABA_A$ receptor activity

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

Allopregnanolone (ALLO) typically enhances $GABA_A$ calming effects

In some individuals, ALLO exacerbates anxiety and compulsivity

Sepranolone normalizes $GABA_A$ receptor activity without interfering in GABA signaling

$GABA_A$: ϒ-aminobutyric acid type A; **ALLO:** Allopregnanolone

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[1]

Tourette Syndrome

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

US prevalence 350-450K children[3]

Essential Tremors

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

US prevalence 6.4 MM people[2]

Obsessive-Compulsive Disorder and related disorders

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

US prevalence 8.2M people[4]

1. 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; **2.** 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; **3.** 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; **4.** International OCD Foundation. "International OCD Foundation | Who Gets OCD?" International OCD Foundation, 16 Dec. 2024, iocdf.org/about-ocd/who-gets-ocd. **PWS:** Prader-Willi syndrome; **ET:** Essential Tremor; **OCD:** Obsessive Compulsive Disorder

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

H1 2026

Initiation of Pilot Phase 2 study in Prader-Willi Syndrome

Focus on evaluating early proof-of-concept

PWS: Prader-Willi syndrome

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

As of June 30, 2025

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

Q4 2025

NDV-01	Planned FDA interactions, manufacturing build-out
Sepranolone	Planned FDA interactions, product supply expansion

H1 2026

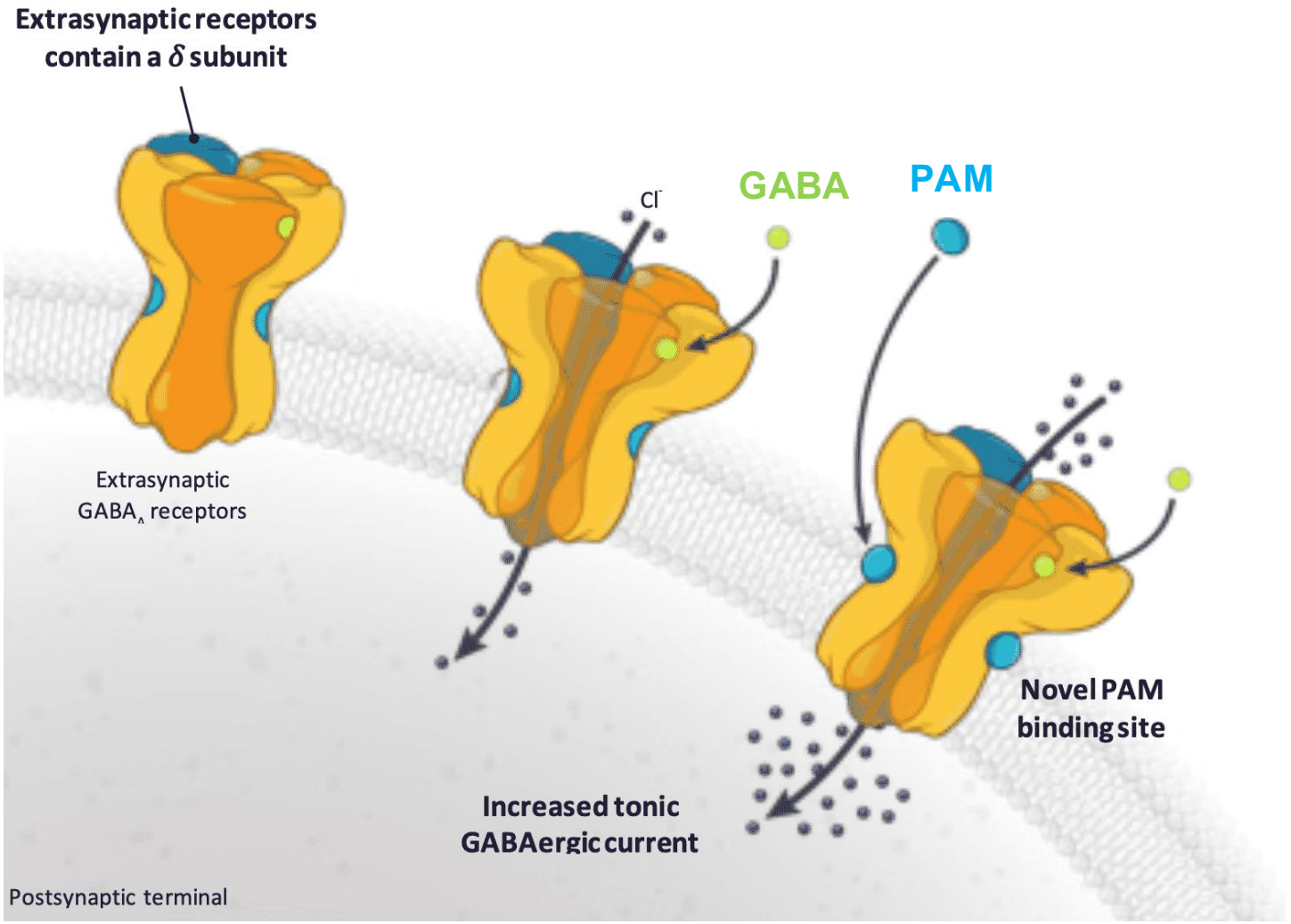
NDV-01	Initiate registration-track study
Sepranolone	Initiate pilot PWS study

PWS: Prader-Willi syndrome

Thank you!

Appendix

Sepranolone has the potential to normalize $GABA_A$ receptor activity



https://asarinapharma.com/sepranolone/how-does-sepranolone-work/