

Cretostimogene Grenadenorepvec in Urology Practice Workflows

Optimized Administration Supporting Clinical Practice

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Disclosures

- Cretostimogene grenadenorepvec is an investigational intravesical oncolytic immunotherapy and has not been approved for marketing by the U.S. Food and Drug Administration for any indication, including high-risk, BCG-unresponsive, non-muscle-invasive bladder cancer.
- I am a clinical provider in multiple industry-sponsored studies, not a CG Oncology employee, and hold no financial or stock interest in CG Oncology.



Learning Objectives & Overview

-  Understand current treatment landscape for NMIBC
-  Explain how cretostimogene's dual mechanism of action drives tumor lysis and immune activation
-  Understand how cretostimogene's 2-step intravesical instillation workflow is integrated daily urology clinic practice

Risk Adapted NMIBC Treatment¹

Grading Criteria

Low-Risk

- LG Ta
 - Solitary
 - <3 cm
- Inc. PUNLMP



Management

- TURBT + single dose periop chemo
- Office fulguration
- Observation/follow up

Intermediate-Risk

- LG TA
 - Multifocal
 - Recurrent <12 mo
 - >3 cm
- LG T1



- TURBT + selective single dose periop chemo
- Consider adjuvant chemo or BCG with maintenance (1 yr)

High-Risk*

- HG T1
- HG Ta
- CIS



- TURBT + BCG with maintenance (3 yrs)
- Consider radical cystectomy
- Clinical trial

PUNLMP: Papillary Urothelial Neoplasm of Low Malignant Potential; TURBT, Transurethral resection of bladder tumor

* Includes lymphovascular invasion (LVI), variant histology, and prostatic urethral involvement

High Risk NMIBC: Current Intravesical Treatment Landscape

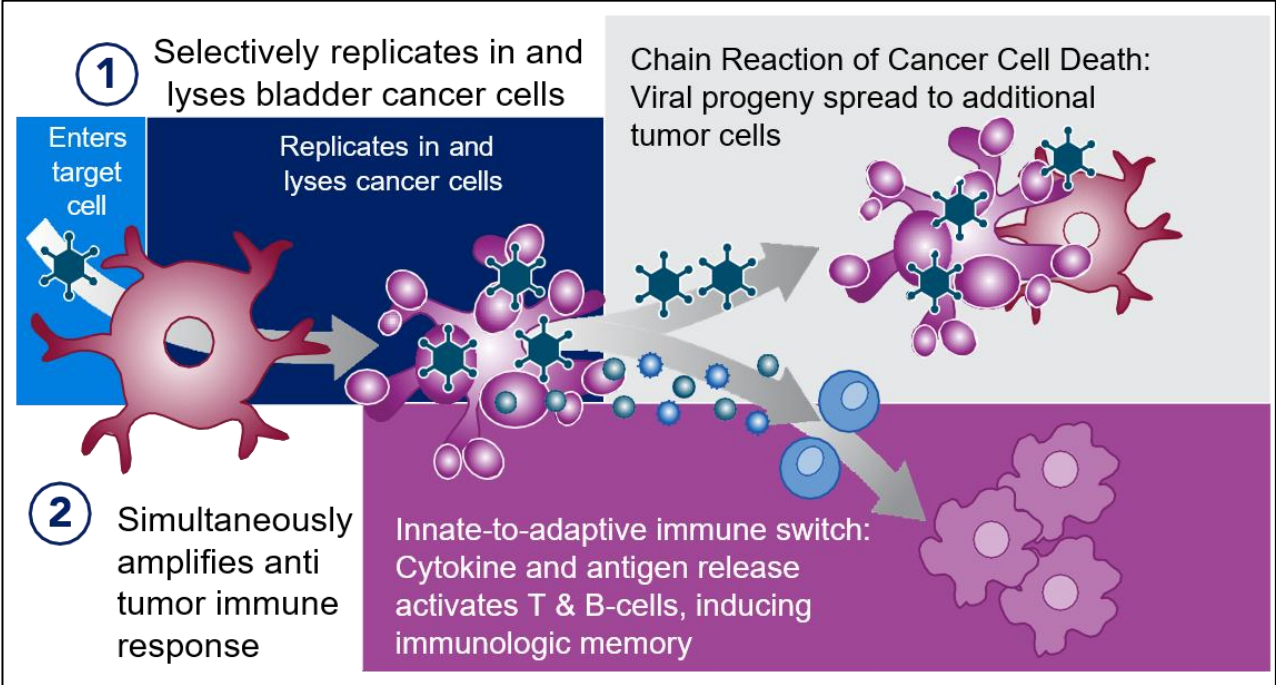
Therapy	FDA-approved NMIBC population
BCG, including TICE	NMIBC, including carcinoma in situ (CIS) and prevention of recurrence of papillary tumors after transurethral resection
Nadofaragene firadenovec (ADSTILADRIN)	HR, BCG-unresponsive NMIBC with CIS, with or without papillary tumors
N-803 (ANKTIVA)+ BCG	BCG-unresponsive NMIBC with CIS, with or without papillary tumors
Gemcitabine releasing system (INLEXZO)	BCG-unresponsive NMIBC with CIS, with or without papillary tumors

BCG: Bacillus Calmette-Guérin; HR: high-risk; LG: low-grade; NMIBC: non-muscle invasive bladder cancer; CIS: carcinoma in situ



Cretostimogene Grenadenorepvec's Dual Mechanism of Action

- Cretostimogene selectively replicates in and lyses bladder cancer cells while amplifying the immune response against bladder tumors
- Novel, effective, well-tolerated intravesical therapy being investigated across intermediate-risk and high-risk NMIBC



	Induction	Optional Reinduction	Maintenance/Follow-Up						Ext. Maintenance/Long-Term Follow-up
Month	0	3	6	9	12	15	18	21	24/30/36
Instillation	<div><div></div><div></div><div></div><div></div><div></div><div></div></div> <div>1 2 3 4 5 6</div>	<div><div></div><div></div><div></div><div></div><div></div><div></div></div> <div>1 2 3 (4 5 6)</div>	<div><div></div><div></div><div></div></div> <div>1 2 3</div>	<div><div></div><div></div><div></div></div> <div>1 2 3</div>	<div><div></div><div></div><div></div></div> <div>1 2 3</div>		<div><div></div><div></div><div></div></div> <div>1 2 3</div>		<div><div></div><div></div><div></div></div> <div>1 2 3</div>

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The Role of DDM

DDM (n-dodecyl- β -D-maltoside) is an excipient administered alongside cretostimogene to enhance adenovirus delivery into tumor cells.



Temporary GAG disruption

DDM temporarily disrupts the glycosaminoglycan (GAG) layer of the bladder.¹



Improved penetration

This allows cretostimogene to more effectively penetrate tumor cells.¹



Preserved urothelium

Urothelium integrity is preserved; DDM showed favorable tolerability in preclinical studies.¹

CORE-008 Cohort A: Cretostimogene Efficacy & Safety Maintained with the 2-Step Process

Who these patients are

- **n=54** high-risk BCG-naïve NMIBC with CIS ± Ta/T1
- **BCG-naïve:** no prior BCG, none within 24 months, or 1–2 doses at most
- **Randomized**
 - Optimized 2-step
 - Original 5-step

Efficacy: 2-step matched 5-step

- Efficacy maintained across groups
- **Optimized 2-step:** 88.0% CR; n=22/25
- **Original 5-step:** 79.2% CR; n=19/24

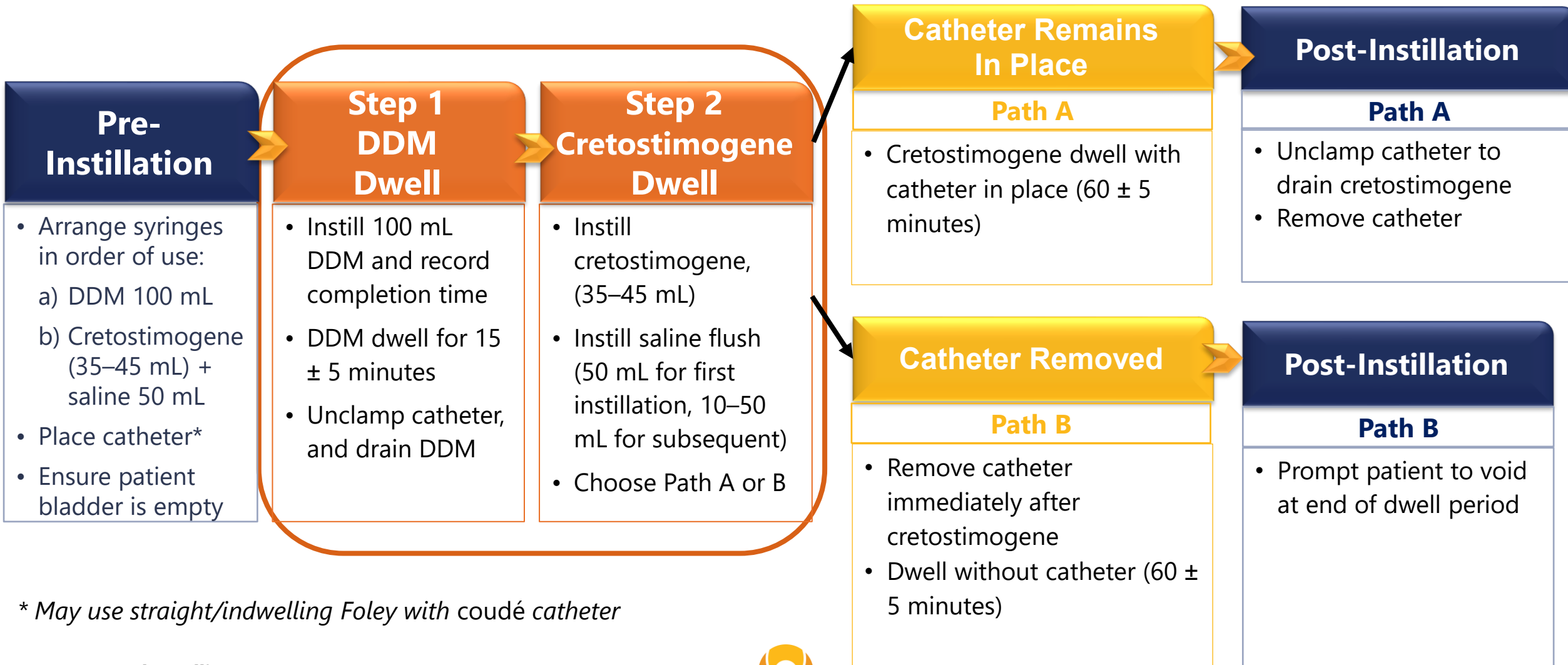
Safety

- Most treatment-related adverse events (TRAEs) were **mild to moderate and localized to bladder**
- No treatment related discontinuations
- 98.1% (53/54) completed all protocol-defined treatments
 - 2-step: 100% (27/27)
 - 5-step: 96.3% (26/27)

BCG: *Bacillus Calmette-Guérin*; CI: *confidence interval*; CR: *complete response*; CT: *computed tomography*; MRU: *magnetic resonance urography*; NMIBC: *non-muscle invasive bladder cancer*
CORE-008 Cohort A, high-risk BCG-naïve NMIBC; randomized 1:1 to original 5-step or optimized 2-step administration.



Cretostimogene and DDM 2-Step Instillation



* May use straight/indwelling Foley with coudé catheter



The Cretostimogene Visit Workflow

Before Patient Arrival

Obtain and store treatment (cretostimogene and DDM)

Review patient history

Counsel patient to limit fluid intake and bladder irritants

During clinic visit



Preparation

- Rapid thawing time
- Dilution per protocol
- Handled at Biosafety Level 2



Pre-Instillation

- Patient education
- Supportive care as needed
- No prophylactic medication required



Instillation

- Catheterization (straight or indwelling Foley with coude catheter)
- Performed in-office



Disposal

- Disinfection procedures
- Biohazardous waste stream



AE Management

- Manage local genitourinary symptoms
- Favorable safety profile
- No severe treatment-related adverse events

Follow-Up

Answer patient questions around viral shedding and household exposure

Provide post-treatment care instructions and patient resources

Counsel patients on the importance of communicating side effects



Adverse Events and Management

Treatment-Emergent Adverse Events

Reported in <10% of BOND-003 C and CORE-008 A patients:

- Bladder spasm
- Dysuria
- Pollakiuria (frequency)
- Hematuria
- Fatigue*
- Urgency**

Patient Education

- Avoid fluid intake 4 hours before instillation
- Avoid bladder irritants

Other Techniques

- Supportive care (e.g., antispasmodics) may be administered before or after treatment if deemed necessary but **not required**
- Other measures can be implemented per provider order

Most treatment-related adverse events are mild to moderate and localized to the bladder.



Follow-Up and Patient Education

For 7 days after every treatment, patients should follow these precautions:



Hygiene

- Proper hand washing and housekeeping hygiene



Bathroom & Waste Precautions

- Minimize/avoid direct contact with urine
- Add bleach to toilet water
- Close lid before flushing
- Disinfect the seat



Sexual Activity & Contraception

- Highly effective birth control and barrier methods must be used during sexual activity



Close Contact with Others

- Close contact (kissing, hugging) is fine if symptom-free
- Avoid contact with others up to 2 weeks if febrile illness, respiratory symptoms, or diarrhea are present



Key Takeaways

- Collaboration between nurses/associates and urologists is key to safely and efficiently integrating cretostimogene into intravesical treatment workflows
- Nurses and associates play a central role in delivery, monitoring, and patient education about intravesical cretostimogene
- Cretostimogene's optimized 2-step process reduces procedural complexity while retaining efficacy
- Data from BOND-003 Cohort C and CORE-008 Cohort A suggest cretostimogene is an effective, well-tolerated intravesical therapy for the treatment of HR NMIBC, a population for whom a choice of effective and safe treatment choices has been lacking



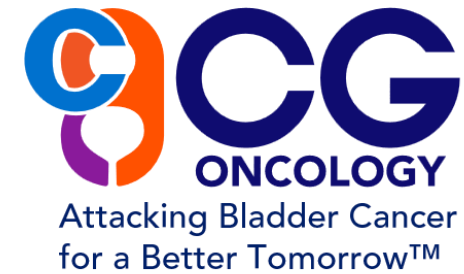
THANK YOU

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BCG Unresponsive NMIBC

FDA-recognized BCG-unresponsive population¹

- High-grade T1 disease at the first evaluation following induction BCG alone
- Recurrent high-grade Ta/T1 disease within 6 months of completion of adequate BCG
- Persistent or recurrent CIS, with or without high-grade Ta/T1 disease, within 12 months of completion of adequate BCG

Adequate BCG (5+2)¹

At least 5 of 6 doses of an initial induction course *and either*

- At least 2 of 3 maintenance doses,
or
- At least 2 of 6 doses of a second induction course

FDA: Federal Drug Administration; BCG: Bacillus Calmette-Guérin; NMIBC: non-muscle invasive bladder cancer; CIS: carcinoma in situ

1. U.S. FDA, 2018.

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BOND-003 Cohort C: Evidence of Cretostimogene's Efficacy and Safety

THE LANCET
Oncology

Efficacy¹

- **n=110** high-risk BCG-unresponsive NMIBC with CIS ± Ta/T1
- **75.5%** complete response at any time (83/110; 95% CI, 66.3–83.2)
- **Median duration of response:** 27.9+ months (95% CI, 14.3–NE)
- **24-month cystectomy-free rate:** 81.3%

Safety¹

- Most treatment-related adverse events (TRAEs) were **mild to moderate and localized to bladder**
- Median time to resolution of grade 1–2 TRAEs: one day
- Dose delays and interruptions were rare

Durable local activity with a tolerability profile that keeps patients on schedule.

CI: confidence interval; GM-CSF: granulocyte-macrophage colony-stimulating factor; NE: not evaluable; TRAE: treatment-related adverse event

1. Tyson et al., 2026.

