

Cystectomy-Free Survival Following Cretostimogene Grenadenorepvec in High-Risk BCG-Unresponsive NMIBC with CIS: Results from the Phase 3 BOND-003 Trial (Cohort C)

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Disclosures

Consultant or Advisory Role

Janssen, Merck, Ferring, BMS, CG Oncology, AstraZeneca, Photocure, Abbvie, Astellas, enGene, Pfizer

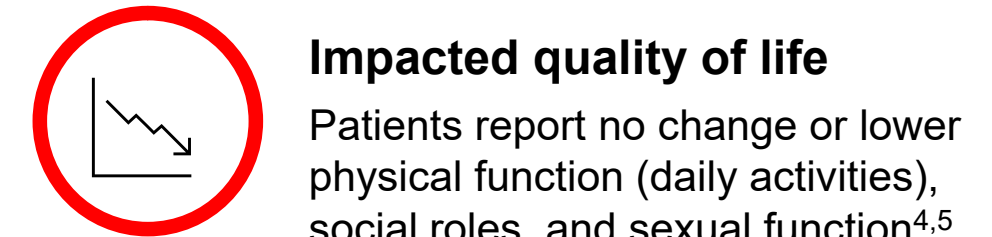
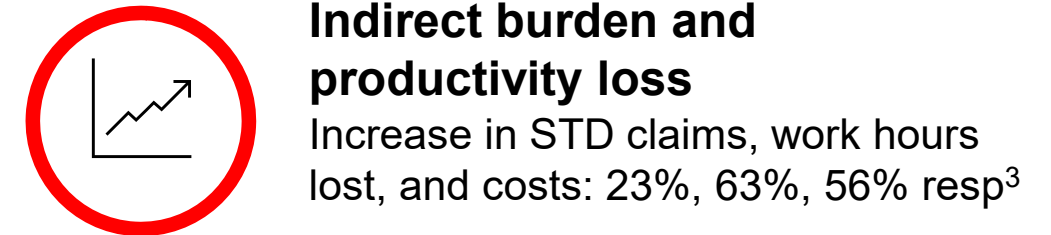
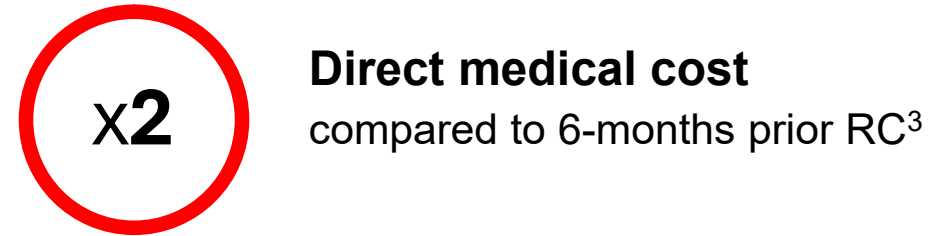
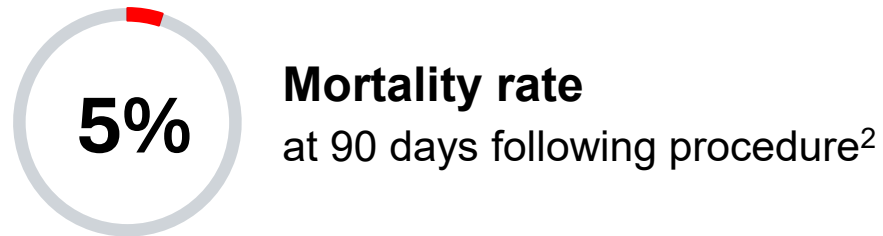
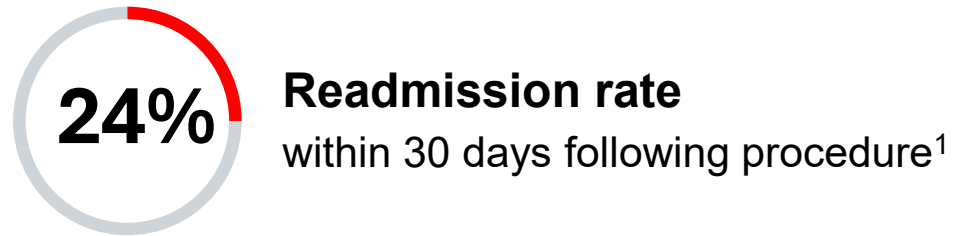
Clinical Trials

CG Oncology, Pfizer, enGene, Theralase, BMS, Janssen

Leadership/Board

GU Co-Chair, Canadian Clinical Trials Group
Member, GU Steering Committee, NIH

Radical Cystectomy Outcomes



Cystectomy-free survival is an important complementary endpoint that captures both disease control and bladder preservation for patients with high-risk BCG-unresponsive NMIBC

BCG: Bacillus Calmette-Guérin; NMIBC: non-muscle invasive bladder cancer; RC: radical cystectomy; STD: short term disability

References: [1]. Chappidi MR, et al. Urol Oncol. 2023; 8: 355e19-28. [2]. Maibom SL, et al. BMJ Open 2021;11:e043266. [3]. Tkacz J, et al. JOURNAL OF MEDICAL ECONOMICS 2024; 27: 963-71. [4]. Rogers Z, et al. BJU Int 2024; 133: 460-473 [5]. Gore JL, et al. J Urol 2025; 213(5S2): e3-4.



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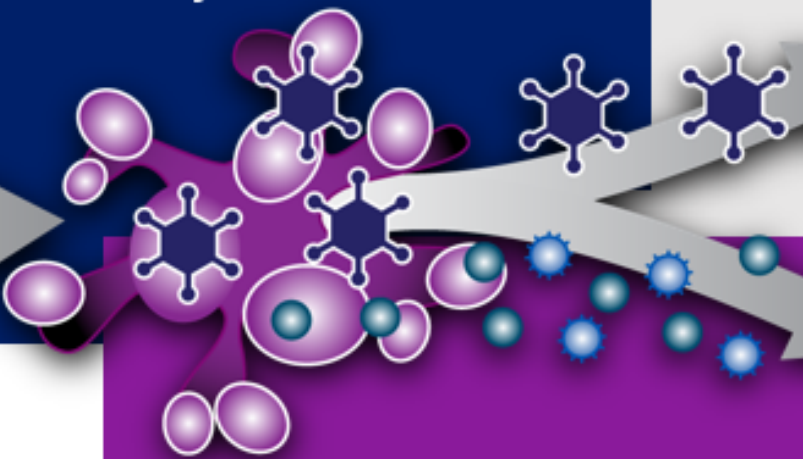
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Oncolytic Immunotherapy: Cretostimogene Grenadenorepvac's Dual Mechanism of Action

- 1 Selectively Replicates in and Lyses Bladder Cancer Cells

Enters target cell

Replicates in and lyses cancer cells

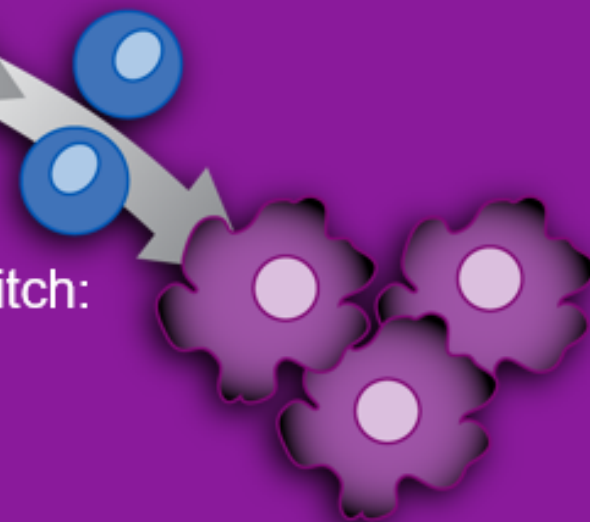


Chain Reaction of Cancer Cell Death:
Viral progeny spread to additional
tumor cells



- 2 Simultaneously Amplifies Anti-tumor Immune Response

Innate to Adaptive Immune Switch:
Cytokine and antigen release
activates T & B-cells, inducing
immunologic memory



Phase 3 Cretostimogene Monotherapy for High-Risk BCG-Unresponsive NMIBC with CIS

HR BCG-Unresponsive NMIBC

Cretostimogene Grenadenorepvec
Single-Arm, Open-Label, IVE Administration

Primary Endpoint:
CR at Any Time

Population

- Enrollment complete (n=112)
- Pathologically confirmed High-Risk BCG-Unresponsive NMIBC with CIS +/- HG Ta/T1
- All HG Ta/T1 disease resected prior to treatment
- Mandatory biopsies at 12-month assessment²

Study Design / Regimen

Induction Course:
Weekly x 6

Second Induction¹:
Weekly x 6 for non-responders

Maintenance Course:
Weekly x 3 Q3M for Year 1
Weekly x 3 Q6M for Year 2-3

Additional Endpoints

- CR at 12-months
- DoR
- RFS
- PFS
- CFS
- Safety

[NCT04452591](https://clinicaltrials.gov/ct2/show/study/NCT04452591)

CIS = Carcinoma in situ. RFS = recurrence free survival. PFS = progression free survival.

Note: Patients undergo urine cytology and cystoscopy every 3 months for first 2 years, as well as mandatory bladder mapping at month 12.

¹ Second induction course of weekly x 6 for non-responders at month 3. ² All patients required to undergo mandatory, systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR



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Patient Demographics & Baseline Characteristics

Subjects in Safety Dataset	N=112	%
Gender		
Male	83	74.1
Female	29	25.9
Age (Years)		
Mean (SD)	72.9 (9.19)	
Median (Range)	74.0 (43-90)	
Age (Categories)		
< 65	19	17.0
≥ 65 and < 75	43	38.4
≥75	50	44.6
BCG History: No. of Prior Instillations		
Median (Range)	12 (7 – 66)	
HR NMIBC T-Stage at Study Entry		
CIS with HG Ta/T1	22	19.6
CIS alone	90	80.4
Prior Therapy Other Than BCG, n (%)		
≥ 1 Prior Therapy	53	47.3
Serial Adjuvant Chemotherapy	34	30.4
Systemic Immunotherapy	7	6.3

- Majority of patients are:
 - Male (74%)
 - White (62%)
 - > 65 years (83%)
- 63.4% of patients in US
- **Highly pre-treated population**
 - Prior chemotherapy (41%)
 - Systemic Immunotherapy (6%)

Efficacy data cutoff as of 23JUN2025

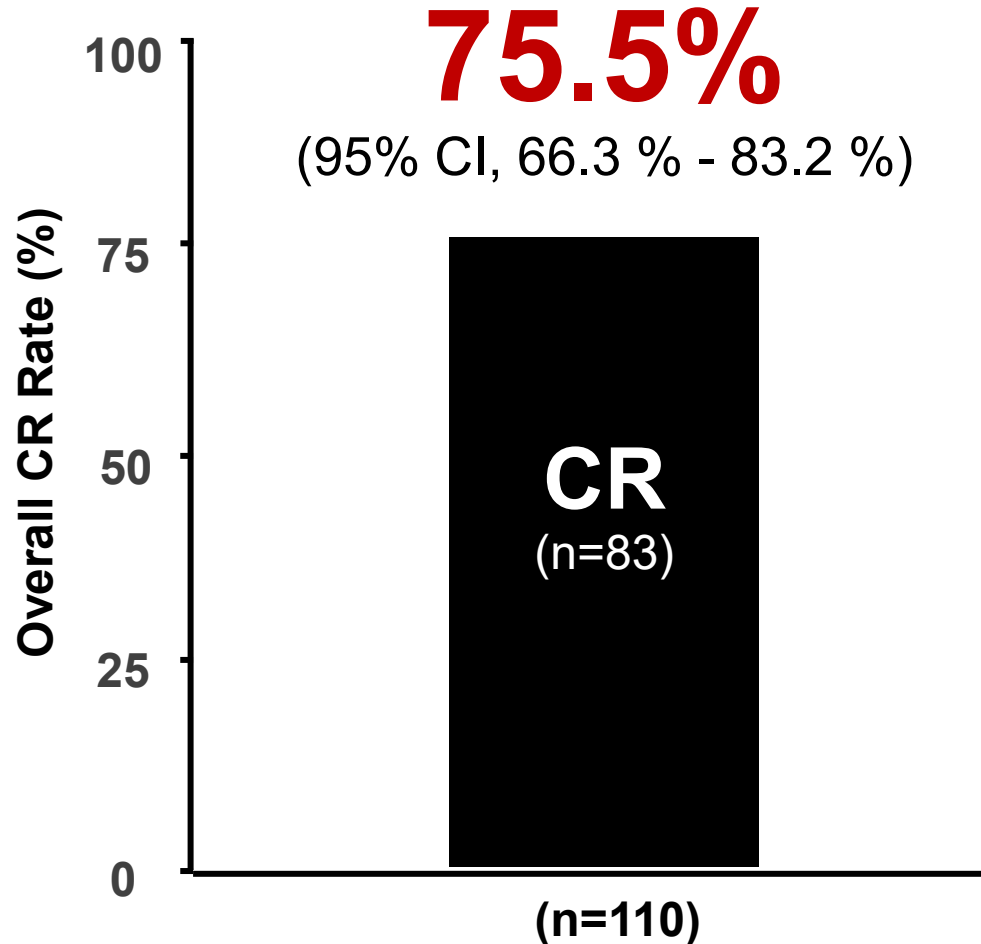


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Consistent and Compelling CR & 24-Month Durability Data

Complete Response at Anytime



CR Landmark	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
12-month	46.4% (36.8, 56.1) <i>51 out of 110 patients</i>	50.7% (40.9, 59.8)
24-month ¹	41.8% (32.5, 51.6) <i>46 out of 110 patients</i>	42.4% (32.7, 51.7)

- Median DOR: 27.9 months (95% CI 14.3-NE%) and ongoing
- 96.4% (106/110) free from progression to \geq T2 disease
- All CRs centrally confirmed*
 - Local : Central concordance: 97.1% of assessments

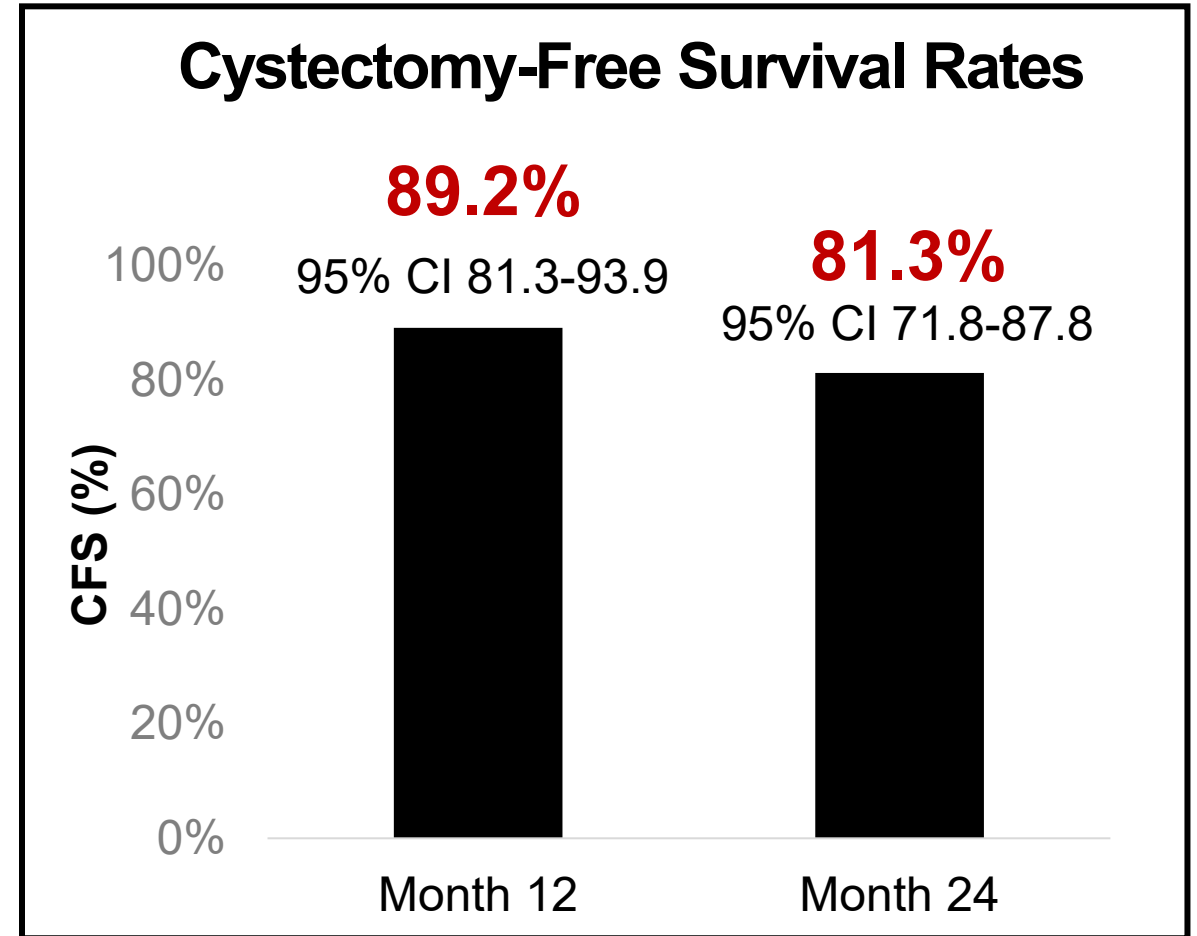
Efficacy data cutoff as of 23JUN2025. Efficacy analysis centrally confirmed. All patients have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance..

*CR is defined as having a negative cystoscopy, a negative urine cytology, and a negative biopsy. In addition, all patients at 12-month timepoint undergo mandatory, systematic bladder mapping of 5 locations, biopsy of the prostatic urethra, and upper tract imaging to confirm CR and detect potential occult disease in the bladder.

Analysis based on both landmark CR rate assessed in clinical trial and CR by Kaplan-Meier estimate.

BOND-003 Cohort C Radical Cystectomy Outcomes

- 83.6% (92/110) did not undergo RC post recurrence or progression
- Median CFS not reached in the efficacy analysis set or any subgroups
- Cystectomy-free rates at key landmarks
 - 12-month: 89.2% (95% CI 81.3-93.9)
 - 24-month: 81.3% (95% CI 71.8-87.8)



Based on Kaplan–Meier estimates;
Cystectomy-free survival defined as time from first dose to radical cystectomy or censoring



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Radical Cystectomy Without Compromising Oncologic Outcomes

Patients undergoing a cystectomy post recurrence or progression, n (%)	
Anytime after first recurrence	18 (16.4%)
Within the first year of recurrence	17 (15.5%)
Time to cystectomy post recurrence or progression (weeks)	
Median (Q1, Q3)	20.0 (14.4, 26.7)
Stage at cystectomy, n (%)	
T0	1 (0.9)
CIS	9 (8.2)
HG Ta	1 (0.9)
T1	4 (3.6)
T2A	1 (0.9)
T2B	1 (0.9)
N2	1 (0.9)

Bladder preservation achieved without compromising the window for curative surgery

- 18/110 (16.4%) patients underwent RC
- 15/18 (83.3%) were T0 or NMIBC

RC: radical cystectomy; NMIBC: non-muscle invasive bladder cancer; TRAE: treatment-related adverse event



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Favorable and Well-Tolerated Safety Profile

Preferred Term (MedDRA v.26.1)	Cretostimogene (n=112)	
	Any Grade (%)	Grade ≥ 3
Patients with ≥ 1 TRAE	71 (63.4%)	0 (0)
Treatment-Related AE reported in > 10% patients		
Bladder Spasm	28 (25.0%)	0 (0)
Pollakiuria	25 (22.3%)	0 (0)
Urgency	23 (20.5%)	0 (0)
Dysuria	21 (18.8%)	0 (0)
Hematuria	15 (13.4%)	0 (0)

- Most AEs were Grade 1-2
- **0% Grade ≥ 3 TRAEs or deaths**
- **Median time to TRAE resolution: 1 day**
- **No treatment related discontinuations**
- 1.8% (n=2) had serious treatment-related AEs (Grade 2)¹
- 97.3% received all protocol defined treatments

¹Treatment-related SAEs were noninfective cystitis (Grade 2) and clot retention (Grade 2). Unrelated AE leading to treatment discontinuation was Hematuria (Grade 2).



Key Takeaways

- Highly effective, well-tolerated, and durable
- Most patients avoided cystectomy
- Low progression rates and NMIBC predominance on final pathology post cystectomy
- Future and ongoing clinical trials are evaluating cretostimogene monotherapy, and rational combinations, as a backbone therapy for NMIBC



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Manuscript In Press at Lancet Oncology

THE LANCET
Oncology

Tyson MD II, Nam J-K, Joshi SS, Uchio EM, Jung SI, Bivalacqua TJ, Steinberg GD, Shore ND, Burke JM, Kitamura H, Tran B, Li R.
Efficacy and safety of intravesical cretostimogene grenadenorepvec oncolytic immunotherapy in high-risk, BCG-unresponsive non-muscle-invasive bladder cancer with carcinoma in situ: a single-arm, phase 3 monotherapy trial (BOND-003 Cohort C). *Lancet Oncol.* In press.



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THANK YOU

All Bladder Cancer Patients and Their Families
Key Investigators, Study Coordinators, Nurses

Co-Authors and Collaborators

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