Efficacy and Safety of Intravesical Cretostimogene Grenadenorepvec Plus Gemcitabine in High-Risk BCG-Exposed Or BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer (CORE-008 Cohort CX)

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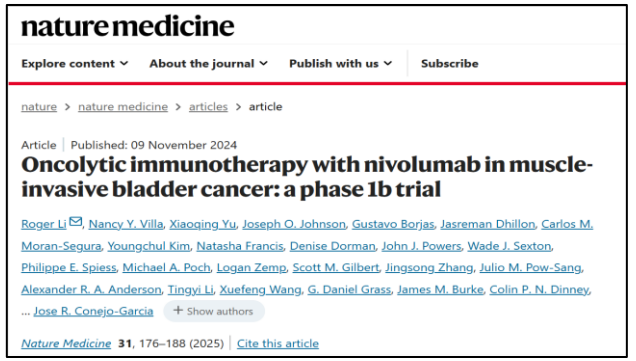
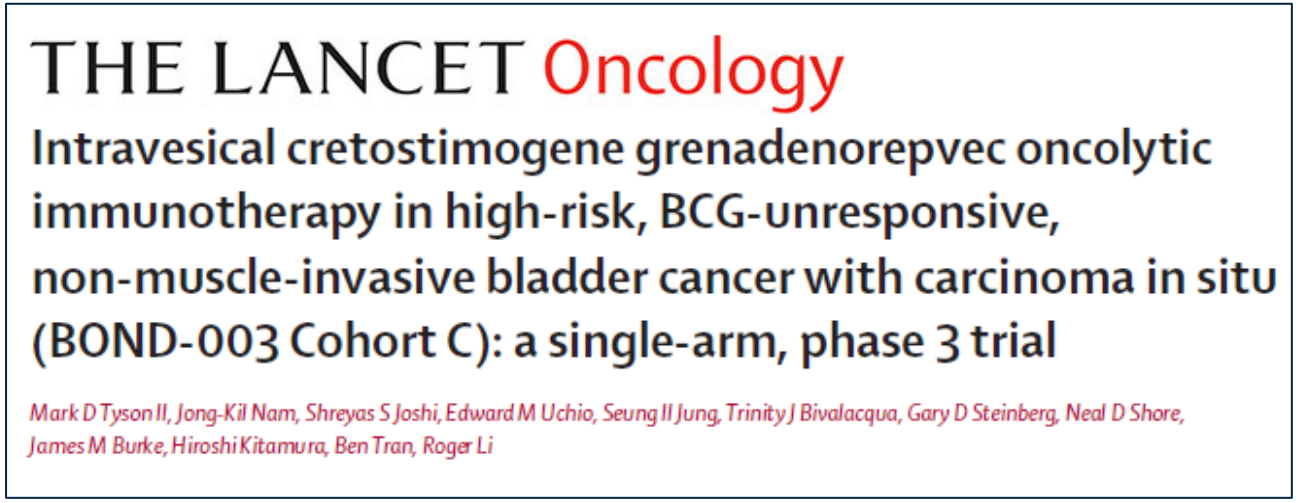
- Consultant or Advisor: CG Oncology, J&J, Astellas, AstraZeneca, Ferring Pharmaceutical
- Equity stock/options: Immunity Bio, Relmada, Caretaker Medical, Euphrates Vascular, Aveera Medical, Icarus, and SafKan Health.

- Study PI : CG Oncology, Ferring Pharmaceuticals

Rationale for Novel Intravesical Combination Strategies in HR-NMIBC

- Published evidence supports efficacy and safety of cretostimogene monotherapy and in combination with pembrolizumab for HR BCG-UR NMIBC and nivolumab for MIBC.[1-3]
- Novel intravesical therapeutic approaches that leverage complementary mechanisms and immune-modulating synergy are still needed for HR NMIBC.
- Pre-clinical data supports mechanistic rationale for combining intravesical gemcitabine and cretostimogene.

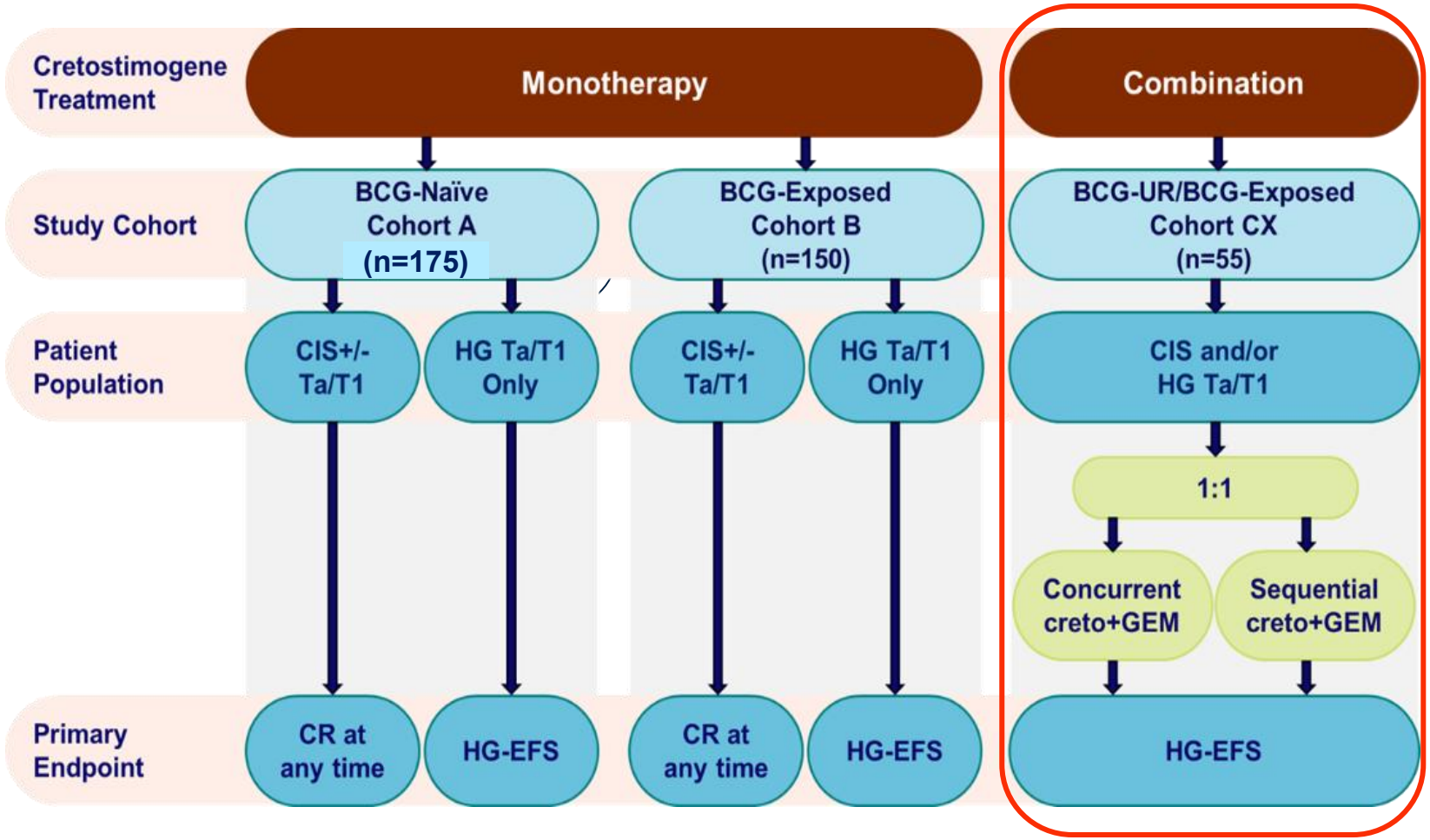




IVE=intravesical

1. Tyson M, et al. *Lancet Oncology* 2026. 2. Li R, et al. *Nat Med* 2024;30(8):2216-2223 3. Li, R, et al. *Nat Med* 2025; 31(1):176-188

Phase 2, Multi-Cohort Trial in HR NMIBC



CIS= Carcinoma in Situ; CR=Complete Response; GEM= Intravesical Gemcitabine; HG-EFS= High-Grade Event-Free Survival
HG-EFS defined as High-grade recurrence/persistence, progression to T1, progression to T2+ and death from any cause
Concurrent: Same-day administration of cretostimogene (first) followed by gemcitabine throughout induction and maintenance.
Sequential: Two weekly cretostimogene instillations followed by one gemcitabine instillation (Weeks 1, 2, 4, 5 vs Weeks 3, 6), continued in maintenance.

BCG-Exposed

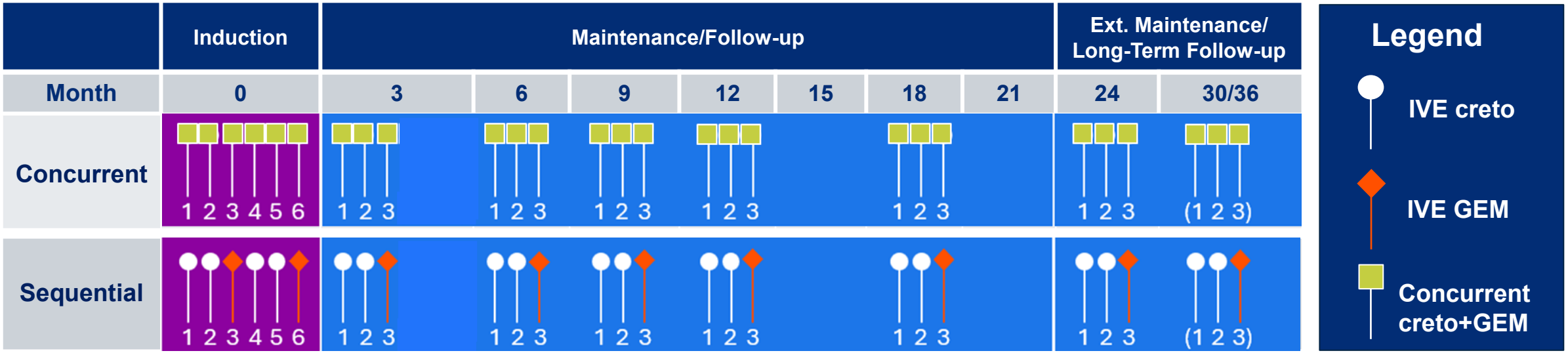
Patients who had prior BCG and either presented with CIS/HGTa recurrence at first evaluation (BCG-resistant), recurred outside of the BCG-unresponsive window following adequate BCG, or recurred within 24 months after inadequate BCG

BCG-Unresponsive

Participants who received adequate BCG (5+2) and present with:

- HG T1 at first evaluation following induction course
- HG Ta/T1 within 6 mo
- CIS within 12 mo

CORE-008 Cohort CX Treatment and Assessment Schedule



- Re-induction allowed for patients with HG Ta and/or CIS at Month 3
- Assessments include: Cystoscopy & Cytology every 3 months; CT/MRU every 6 months
- Clinic-based instillation with flexibility to void at home after instillation during maintenance

Concurrent: Same-day administration of cretostimogene (first) followed by gemcitabine throughout induction and maintenance.
Sequential: Two weekly cretostimogene instillations followed by one gemcitabine instillation (Weeks 1, 2, 4, 5 vs Weeks 3, 6), continued in maintenance.
Efficacy assessments based on local pathology review.

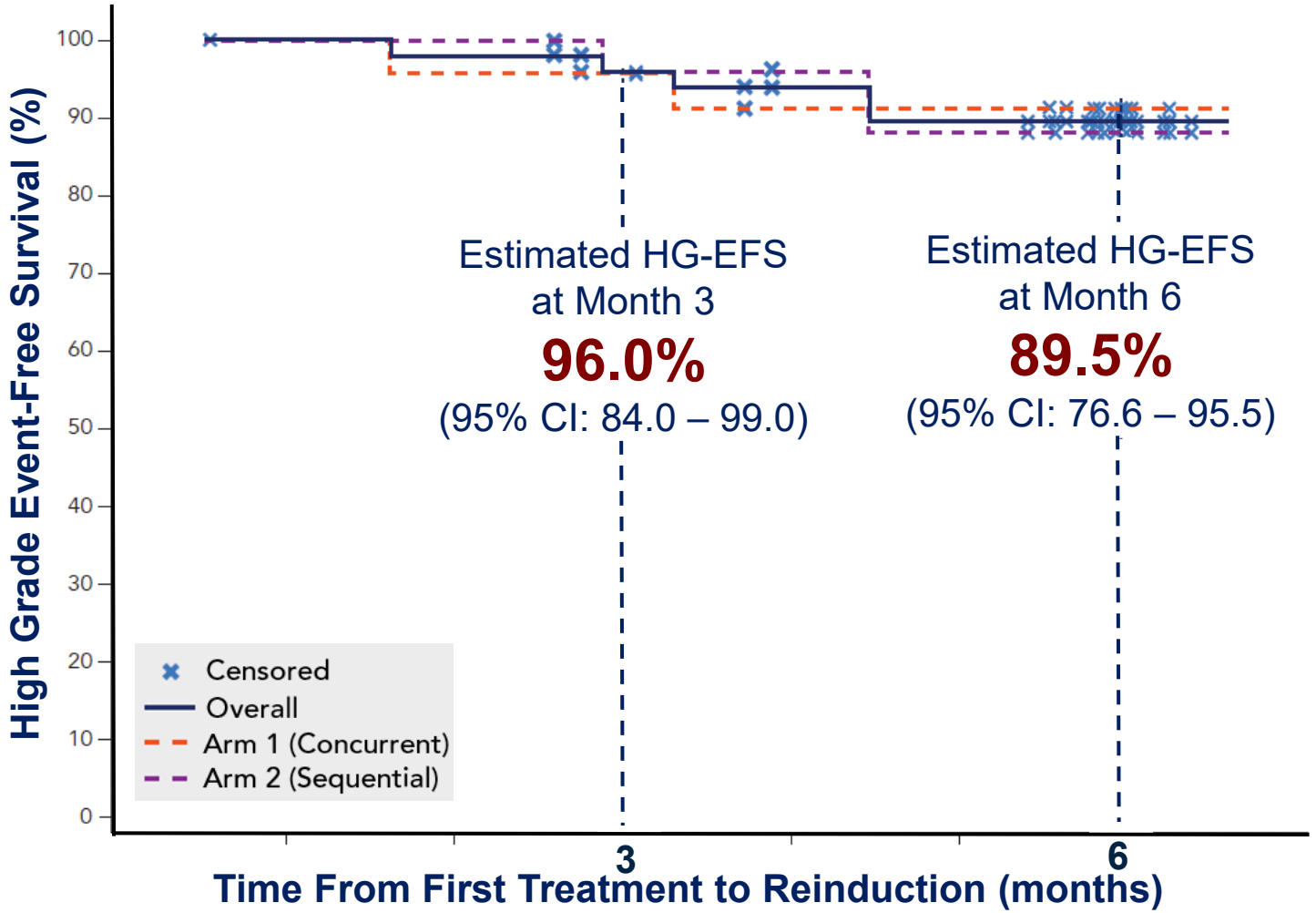
Patient Demographics & Baseline Characteristics

Patients in Safety Dataset	N=55	%
Gender		
Male	43	78.2
Female	12	21.8
Age (Years)		
Mean (Range)	73.1 (54-88)	
Median (IQR)	75 (66-79)	
Age (Categories)		
< 65	10	18.2
≥ 65 and < 75	17	30.9
≥75	28	50.9
ECOG PS		
0	48	87.3
1	6	10.9
2	1	1.8
HR NMIBC T-Stage at Study Entry		
CIS +/- HG Ta/T1	28	50.9
HG Ta/T1	27	49.1
BCG History, n (%)		
Median BCG doses (IQR)	7.0 (6-13)	
BCG-Exposed	36	65.5
BCG-Unresponsive	19	34.5

- All patients enrolled from the U.S. across multiple sites of care
  - 80.0% community
  - 20.0% academic
- **Majority of patients are:**
  - Male (78.2%)
  - White (92.7%)
  - > 65 years (81.8%)
- **Cohort generally well-balanced across concurrent and sequential treatment arms**

Efficacy data cutoff as of 13MAR2026.

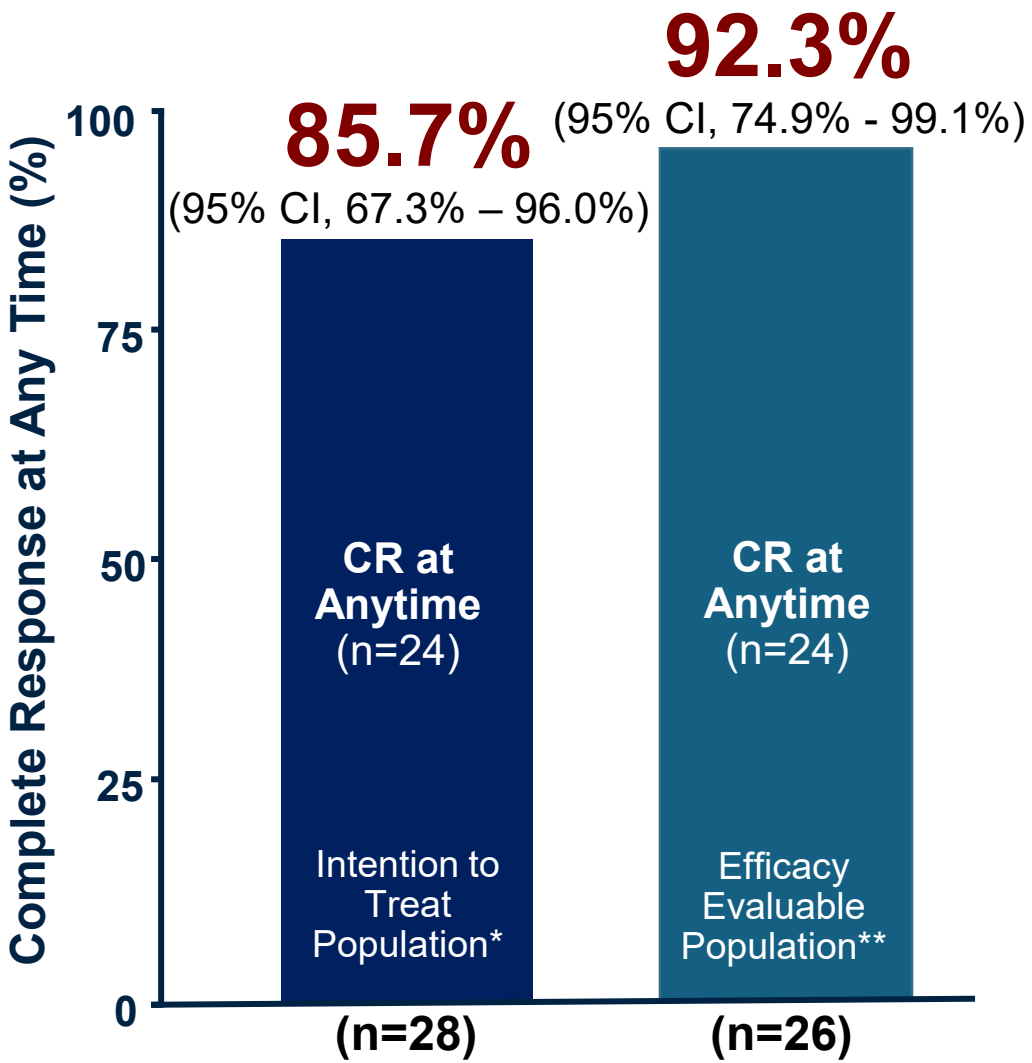
High-Grade Event-Free Survival at 3 and 6-Months From CORE-008 Cohort CX (ITT Population)



- Median follow-up: 6.6 months
- **No significant differences in HG-EFS by arm**
- **Consistent response among BCG-UR and BCG-exposed subgroups**
- No treatment-related progression to MIBC or mUC
  - 2 patients experienced NMIBC stage reclassification

BCG-UR= BCG-Unresponsive; CIS= Carcinoma in Situ; HG-EFS= High-Grade Event-Free Survival; MIBC= Muscle Invasive Bladder Cancer; mUC= Metastatic Urothelial Carcinoma; HG-EFS defined as high-grade recurrence/persistence, progression to T1, progression to T2+ and death from any cause; Efficacy data cutoff as of 13MAR2026; Efficacy assessments based on local pathology review; HG-EFS presented in intention to treat (ITT) population representative of all patients randomized on CORE-008 Cohort CX (Arm 1/Concurrent; Arm 2/Sequential); Two patients with CIS at baseline were found with HGT1 at Month 6.

High Complete Response Rates Within CIS-Containing Population



CR Rate	% (n/N)	95% Confidence Interval
Concurrent	**83.3%** *10 out of 12 patients*	(51.6, 97.9)
Sequential	**87.5%** *14 out of 16 patients*	(61.7, 98.5)

- Includes BCG-Exposed and BCG-Unresponsive patients
- High CR rates were achieved in both concurrent and sequential arms, with overlapping confidence intervals
- CR outcomes were directionally consistent with primary endpoint findings (HG-EFS)

CIS= Carcinoma in Situ; CR=Complete Response
CR defined as having negative cystoscopy, urine cytology, and biopsy (as indicated).
Efficacy data cutoff as of 13MAR2026. Efficacy assessments based on local pathology review.
* Intention to treatment (ITT) population includes all participants who are randomized in Cohort CX (Arm 1/Concurrent; Arm 2/Sequential).
** Efficacy evaluable population includes patients who have received at least four doses of cretostimogene, meet the definition of BCG-Unresponsive/BCG-Exposed and have completed a protocol-defined efficacy assessment at Month 3

Favorable and Well-Tolerated Safety Profile

Preferred Term (MedDRA v.26.1)	Overall (n=55)	
	Grade 1-2 n (%)	Grade ≥ 3 n (%)
Patients with ≥ 1 TRAE	36 (65.5 %)	0 (0)
Treatment-Related AE reported in ≥ 10% patients		
Bladder Spasm	26 (47.3)	0 (0)
Dysuria	19 (34.5)	0 (0)
Pollakuria	14 (25.5)	0 (0)
Fatigue	10 (18.2)	0 (0)
Micturition Urgency	8 (14.5)	0 (0)
Hematuria	6 (10.9)	0 (0)

- **0% Grade ≥ 3 TRAEs, SAEs or deaths**
- 85.5% (47/55) completed all protocol-defined treatments
  - Arm 1 (Concurrent)- 71.4% (20/28)
  - Arm 2 (Sequential)- 100% (27/27)
- **No patients discontinued on Arm 2 (sequential) due to TRAE**
- 4 patients withdrew from Arm 1 (concurrent) for persistent grade 1-2 localized TRAEs
- No difference in the proportion of patients with AEs between arms

AE= adverse events; SAE= Serious adverse events; TRAE=treatment-related adverse events
Safety Data Cutoff Date 13MAR2026
Concurrent: Same-day administration of cretostimogene (first) followed by gemcitabine throughout induction and maintenance.
Sequential: Two weekly cretostimogene instillations followed by one gemcitabine instillation (Weeks 1, 2, 4, 5 vs Weeks 3, 6), continued in maintenance.

CORE-008 Cohort CX: Summary and Conclusions

- The combination of cretostimogene and gemcitabine demonstrates **robust clinical efficacy and safety** in BCG-exposed and BCG-unresponsive NMIBC
- **Comparable efficacy** observed in both concurrent and sequential arms
- Sequential administration of intravesical cretostimogene and gemcitabine was **well-tolerated** and supports the feasibility of intravesical-only treatment strategies
- **Continued follow-up is underway** to further characterize longer-term outcomes

CORE-008
COHORT CX

BCAN
20 Years of Impact

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Thank You

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

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