Clinical and Pharmacokinetic/ Pharmacodynamic Insights From CORE-008 Cohort A

PHASE 2 STUDY OF INTRAVESICAL CRETOSTIMOGENE GRENADENOREPVEC IN PATIENTS WITH HIGH-RISK BCG-NAÏVE NON-MUSCLE INVASIVE BLADDER CANCER

Matthew Mossanen, MD, MPH

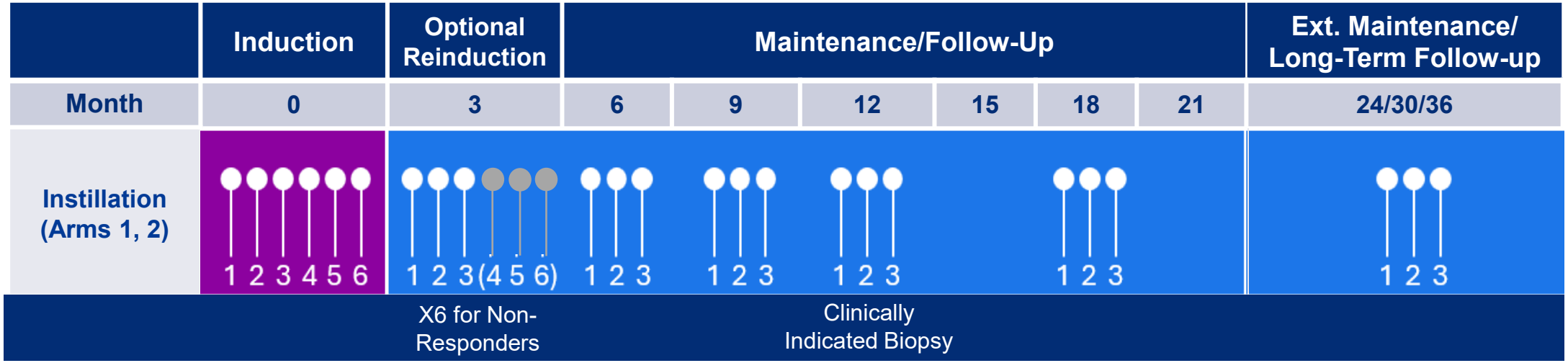
Presented at the New England Section
of the American Urological Association Annual Meeting
October 24, 2026

For individual reference only. The information accessed through this QR code is intended solely for individual reference and should not be altered, modified, or reproduced in any way.

Disclosures

- CG Oncology: Clinical trial investigator, consultant
- Urogen: Advisory board
- Watershed: Steering committee, stocks
- Ferring: Advisory board, research support
- Pfizer: Advisory board
- MGB MIT: Research funding

CORE-008 COHORT A Treatment & Assessment Schedule



- Re-induction allowed for patients with HG Ta and/or CIS at Month 3
- Randomized 1:1 (Original 5-step [Arm 1] or Optimized 2-step [Arm 2] administration)
- Cystoscopy & cytology every 3 months
- Biopsies as clinically indicated at 12 months
- CT/MRU every 6 months
- Year 3: Treatment optional

CIS: carcinoma in situ; CT: computed tomography; HG: high grade; MRU: magnetic resonance urography; Ta: non-invasive papillary carcinoma.

Dana-Farber Cancer Institute | Mass General Brigham

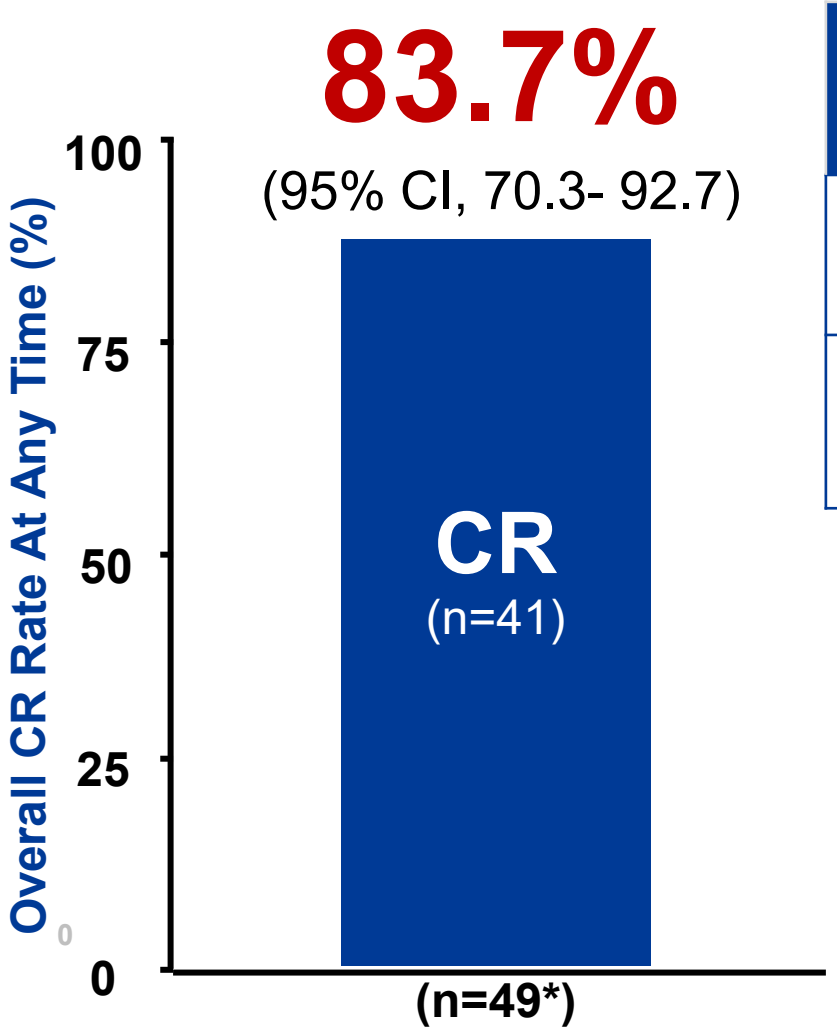
Patient Demographics & Baseline Characteristics

Patients in Safety Dataset	N=54	%
Sex, Male, n, %	49	90.7
Median Age, Years (Range)	73.5	(69-79)
Age, Years, Categories n, %		
< 65	6	11.1
≥ 65 and < 75	22	40.7
≥75	26	48.1
ECOG PS		
ECOG PS 0	44	81.5
ECOG PS 1	10	18.5
HR NMIBC T-Stage at Study Entry, n, %		
CIS alone	24	44.4
CIS with HG Ta	17	31.5
CIS with HG T1	13	24.1
BCG History, n, %		
No Prior BCG	47	87.0
BCG >24 Mo Ago	7	13.0
Prior Adjuvant IVE Chemotherapy, n, %	7	13.0

- **Majority of patients are:**
  - Male (90.7%)
  - White (92.6%)
  - > 65 years (88.8%)
- **All patients enrolled from the U.S.**
- Patient demographics comparable across arms
  - Balanced cohort of HR NMIBC in original vs optimized administration approaches

BCG: bacillus Calmette-Guérin; CIS: carcinoma in situ; ECOG PS: Eastern Cooperative Oncology Group performance status; HG: high grade; HR: high risk; IVE: intravesical; NMIBC: non-muscle invasive bladder cancer; T1: lamina propria-invasive carcinoma; Ta: non-invasive papillary carcinoma.

CORE-008 COHORT A Arms 1 & 2: Initial Response Rates



CR Rate	% (n/N)	Confidence Interval (95% CI)
Original Admin**	**79.2%** *19 / 24 patients*	(57.8, 92.9)
Optimized Admin***	**88.0%** *22 /25 patients*	(68.8, 97.5)

- Median follow-up: 4.6 months
- No patients underwent radical cystectomy
- No treatment-related progression to MIBC or mUC
- No Grade ≥ 3 TRAEs, SAEs, discontinuations, or deaths

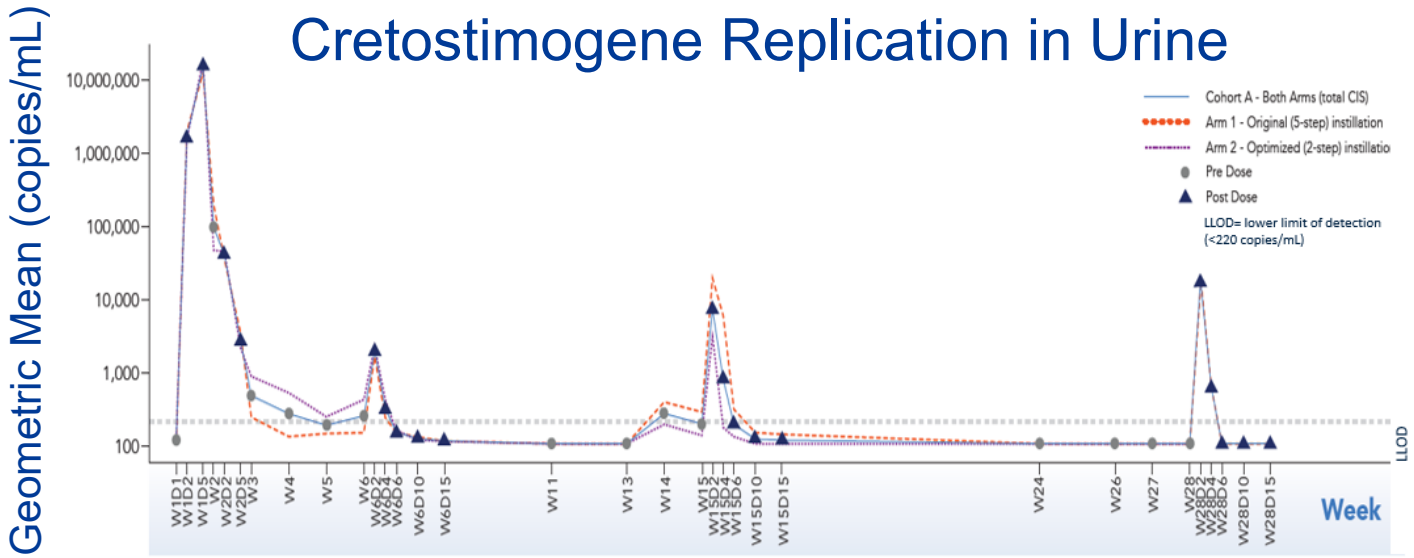
Efficacy data cutoff as of 01SEP2025. Efficacy analysis centrally confirmed. All patients have active disease at baseline prior to enrollment.
* 49 patients were assessed for efficacy at the time of data cutoff. 4 re-induced patients are pending 6-month assessments. ** Original administration included 5-step instillation with series of bladder saline washes followed by DDM and cretostimogene instillations; *** Optimized administration streamlined the process to 2-steps inclusive of DDM followed by cretostimogene instillations ; A CR is defined as having a negative cystoscopy, a negative urine cytology, and a negative biopsy (as indicated). Analysis based on both landmark CR rate assessed in clinical trial and DoR by Kaplan-Meier estimate. CI: confidence interval; CR: complete response; DDM: dodecyl maltoside; DoR: duration of response; MIBC: muscle invasive bladder cancer; mUC: metastatic urothelial carcinoma; SAE: serious adverse event; TRAE: treatment-related adverse event.

Dana-Farber Cancer Institute | Mass General Brigham

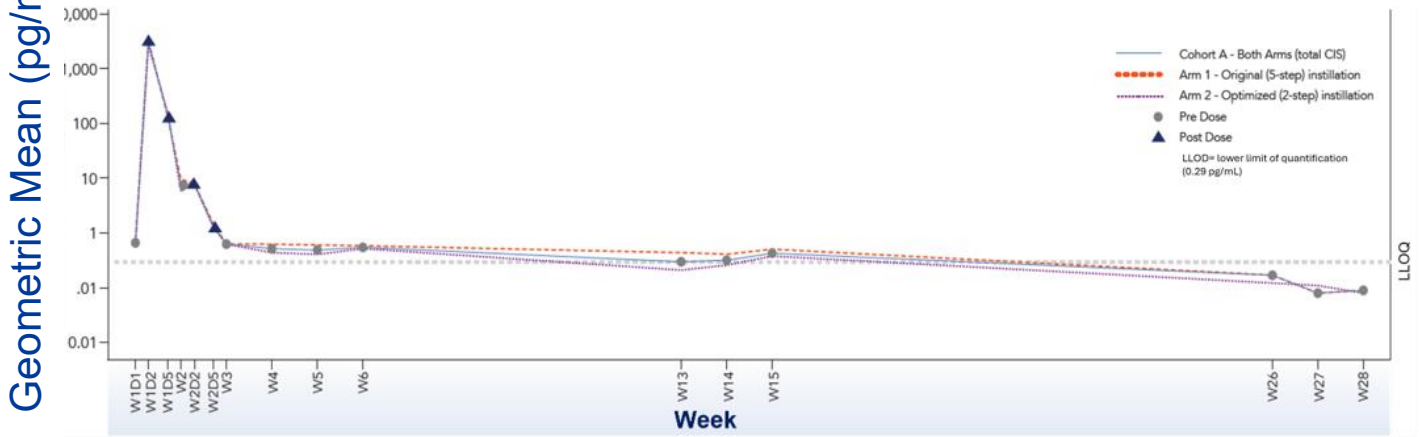
Urinary Pharmacokinetic and Pharmacodynamic Insights

CORE-008 COHORT A

Cretostimogene Replication in Urine



GM-CSF Transgene Expression in Urine



- No detectable creto and low baseline endogenous GM-CSF
- Characteristic peak and trough creto levels during induction and maintenance
- GM-CSF levels increased robustly after first induction dose, indicating successful transgene expression
- Between instillations, GM-CSF levels remain near baseline

creto: cretostimogene grenadenorepvec; GM-CSF: granulocyte-macrophage colony-stimulating factor.

CORE-008 COHORT A Arms 1 & 2: Summary and Conclusions

- Cretostimogene monotherapy demonstrates efficacy, safety, and tolerability in HR BCG-Naïve NMIBC with CIS
- Optimized schedule appears favorable
- Pharmacokinetic/pharmacodynamic and clinical insights reinforce cretostimogene's mechanism of action, treatment schedule, and safety profile
- Findings support continued development of cretostimogene across NMIBC disease states

BCG: bacillus Calmette-Guérin; CIS: carcinoma in situ; HR: high risk; NMIBC: non-muscle invasive bladder cancer.

Bladder Cancer Patients and Their Families

Key Investigators

Study Coordinators

Nurses

CORE-008 COHORT A

For individual reference only. The information accessed through this QR code is intended solely for individual reference and should not be altered, modified, or reproduced in any way.

Research funded by CG Oncology, Inc.

THANK YOU

KEY COLLABORATORS

Colin P. N. Dinney, Rochester, NY

Shane M. Pearce, Spokane, WA

Laurence H. Belkoff, Bala Cynwyd, PA

Brian C. Mazzarella, Austin, TX

Christopher M. Pieczonka, Syracuse, NY

Neal D. Shore, Myrtle Beach, SC

R. Jonathan Henderson, Little Rock, AR

Siamak Daneshmand, Los Angeles, CA

Gary D. Steinberg, Chicago, IL

Trinity J. Bivalacqua, Philadelphia, PA

CG ONCOLOGY

Ying Chen

Pat Keegan

Sarah Donatelli

Sarah Hohl

Shelja Patel

Rob Svatek

Rebecca Tregunna

Vijay Kasturi

Dana-Farber Cancer Institute | Mass General Brigham