Updates to a Patient-Centric Expanded Access Program with Cretostimogene Grenadenorepvec for BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer

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BACKGROUND

- Cretostimogene grenadenorepvec is an oncolytic immunotherapy with dual mechanisms of action (Figure)
- BOND-003 evaluating cretostimogene in HR BCG-UR NMIBC with CIS population showed a 75.5% CR at anytime and median DoR of 27.9 months, with 0% ≥ Grade 3 TRAEs- consistent with previous findings.[1-5]
- Granted US FDA Fast Track and Breakthrough Therapy Designations in HR BCG-UR NMIBC CIS +/- Ta/T1.
- Expanded Access Programs (EAP) are designed to give patients access to potentially beneficial investigational treatments before they are approved.[6]

CRETO-EAP offers cretostimogene for patients with BCG-unresponsive NMIBC with the following considerations

- Ineligible for, or limited access to, other BCG-UR clinical trials
- Unable to tolerate available treatment options
- Limited or restricted access to alternative therapies

Initial Population

- Pathologically confirmed BCG-unresponsive CIS ± HG Ta/T1 NMIBC
- Expanded window for prior intravesical therapy

2026 Protocol Amendment

- Added eligibility for patients with BCG-unresponsive HG Ta/T1 NMIBC without CIS
- Patients who are unable to access BCG and who received adequate Gem/Doce may be eligible upon recurrence

Abbreviations: Creto-EAP: Cretostimogene Expanded Access Program; NMIBC: Non-Muscle-Invasive Bladder Cancer; CIS: carcinoma in situ; HR: high-risk; HG: high-grade; DoR: Duration of Response; EFS: event-free survival; TRAEs: Treatment-Related Adverse Events; SUO: Society of Urologic Oncology; Gem/Doce: Gemcitabine/Docetaxel

CRETO-EAP

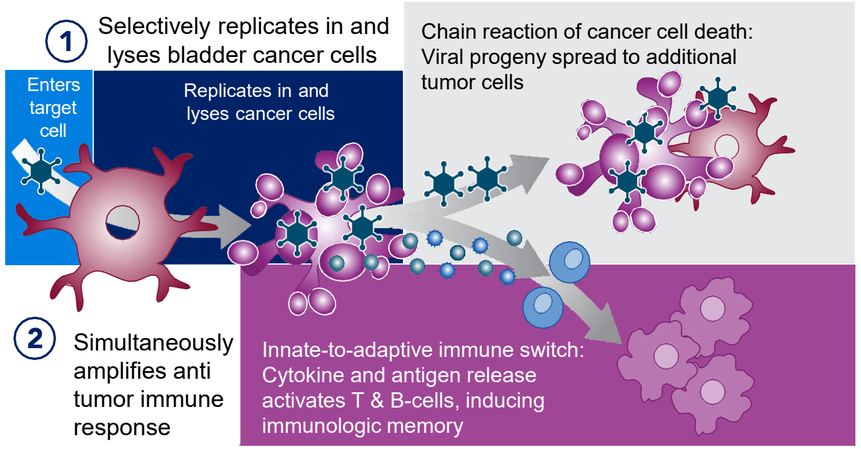
First Patients Treated; Actively Enrolling

Real-World, Expanded Eligibility

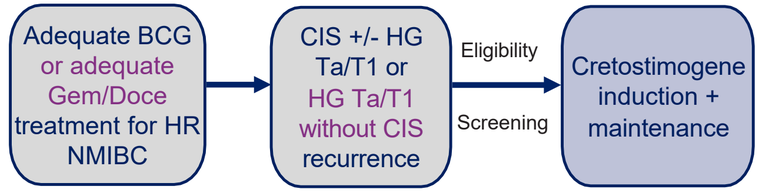
Broad Patient Access Across Community & Academic Sites

ONCOLYTIC IMMUNOTHERAPY

Cretostimogene Grenadenorepvec's Dual Mechanism of Action



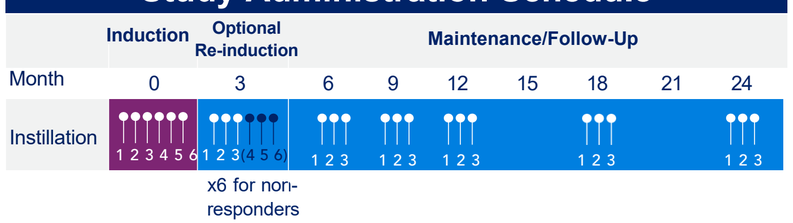
STUDY DESIGN



Purple text indicates protocol amendments

- Eligibility and efficacy based on local assessments
- Primary endpoint: Safety
- Co-secondary endpoints: CR at any time (CIS-containing disease); HG EFS (HG Ta/T1; papillary-only)

Study Administration Schedule



- Partial responders (Mo 6 & beyond) may receive continued treatment at the discretion of the Investigator
- Streamlined post instillation direct close contact instructions
- Patients will be assessed for response during routine NMIBC surveillance, according to AUA/SUO guidelines

To learn more and how to participate, contact: CRETO.EAP@cgoncology.com

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Acknowledgements: Pat Keegan, MD; Shelja Patel, PharmD Sarah Hohl, PhD, & Vijay Kasturi, MD

References: **1** Burke, *J Urol*; 2012, **2** Packiam, *Urol Oncol*; 2018, **3** Li, AUA Meeting; 2022, **4** Li, *Nat Med*; 2024, **5** Tyson, SUO Meeting, 2025; **6** U.S. FDA. Expanded Access

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Bladder Cancer Think Tank
Denver, Colorado

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Attacking Bladder Cancer for a Better Tomorrow™

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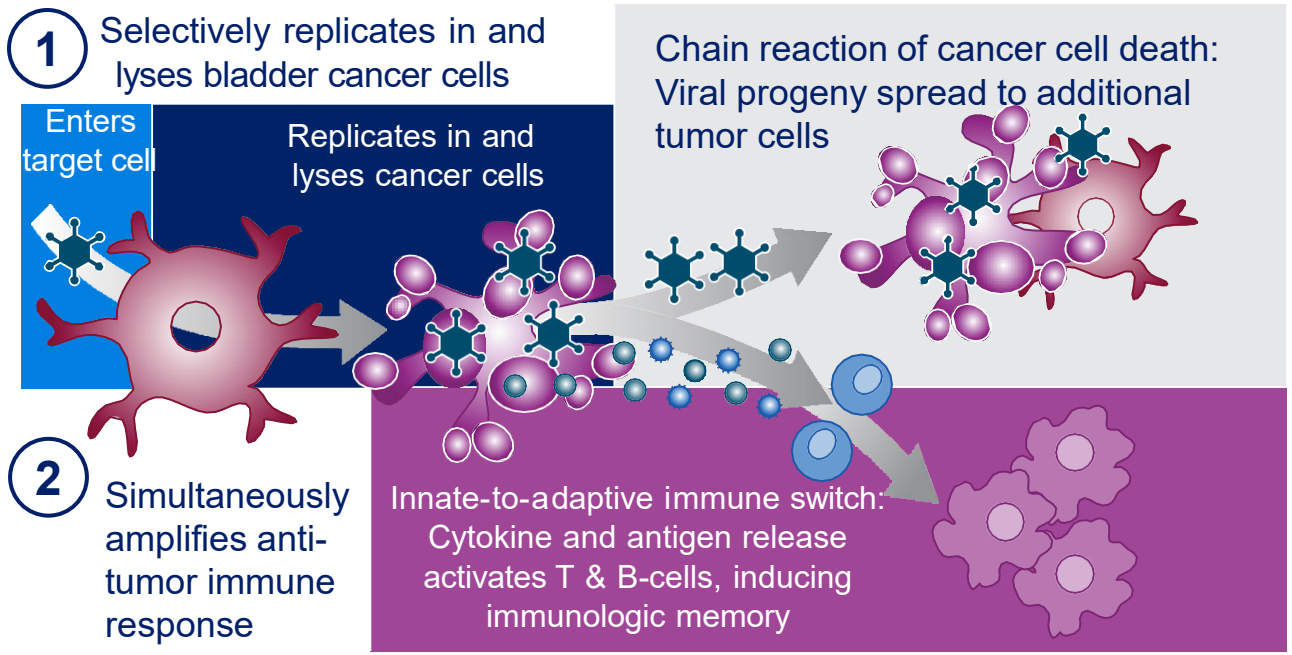
CRETO-EAP

Cretostimogene Grenadenorepvec's Novel Mechanism, Clinical Data, and Regulatory Milestones



Expanded Access Program

A pathway designed to give patients access to potentially beneficial investigational treatments before they are approved

- BOND-003: cretostimogene in HR BCG-UR NMIBC with CIS
  - 75.5% CR at anytime
  - 27.9-month median DoR,
  - 0% ≥Grade 3 TRAEs
- US FDA Fast Track and Breakthrough Therapy Designations in HR BCG-UR NMIBC CIS +/- Ta/T1
- CRETO-EAP
  - Open-label clinical trial
  - Provides cretostimogene to real-world patients otherwise trial-ineligible or who lack access to existing options

Creto-EAP: Cretostimogene Expanded Access Program; CIS: Carcinoma In Situ; NMIBC: Non-Muscle Invasive Bladder Cancer; HR: High-Risk; BCG-UR: Bacillus Calmette-Guerin-Unresponsive; CR: Complete Response; DoR: Duration of Response; TRAE: Treatment-Related Adverse Event; FDA: Food and Drug Administration

CRETO-EAP Eligibility & Trial Design

Initial population

- Pathologically confirmed BCG-unresponsive CIS ± HG Ta/T1 papillary NMIBC
- Expanded window for prior intravesical therapy

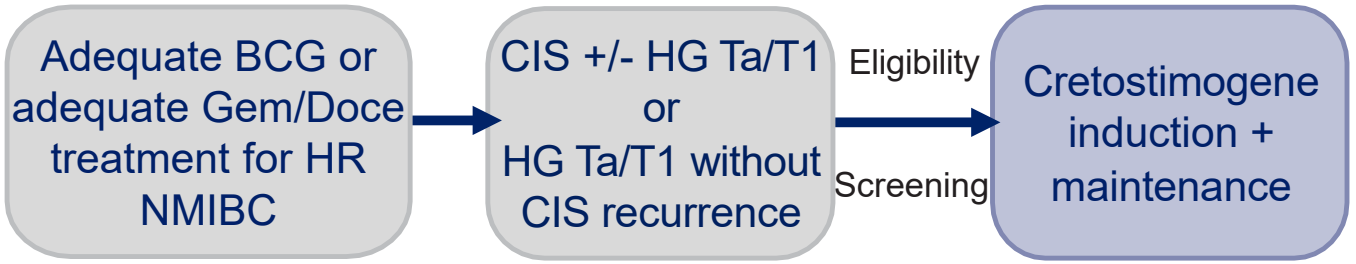
2026 Protocol amendment

Expands eligibility to patients:

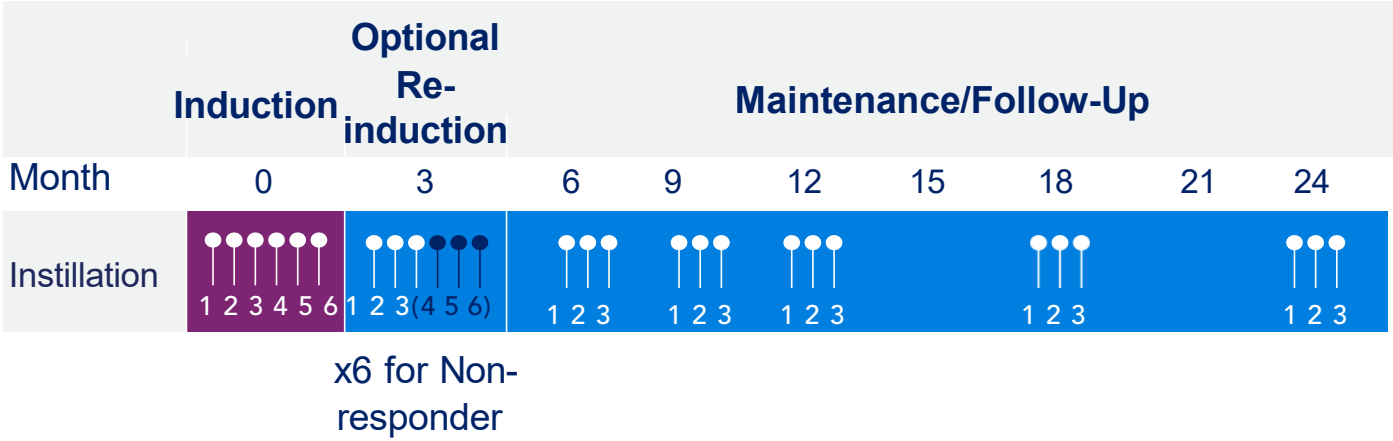
- With BCG-unresponsive HG Ta/T1 NMIBC **without CIS**
- Who are unable to access BCG and who received adequate Gem/Doce may be eligible upon recurrence

- Partial responders may receive continued treatment at investigator discretion
- Patients will be assessed for response during routine NMIBC surveillance

Study Design



Study Administration Schedule



CRETO-EAP Endpoints and Current Status

PRIMARY ENDPOINT	CO-SECONDARY ENDPOINTS	CO-SECONDARY ENDPOINTS
Safety Assessed across all enrolled patients throughout induction, maintenance, and re-induction	**Complete Response at Any Time** for BCG-unresponsive CIS-containing disease.	**High-grade event-free survival** for HG Ta/T1 (papillary-only) disease.

Enrollment Status CRETO-EAP enrollment is ongoing, with safety and clinical experience monitored per protocol.

Conclusion

- The CRETO-EAP protocol amendment broadens eligibility to better align patient access with real-world treatment patterns.
- Findings will help characterize the safety and clinical experience of cretostimogene in a broader, real-world BCG-unresponsive NMIBC population outside of a traditional clinical trial.

To learn more and how to participate, please contact: CRETO.EAP@cgoncology.com