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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
- 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

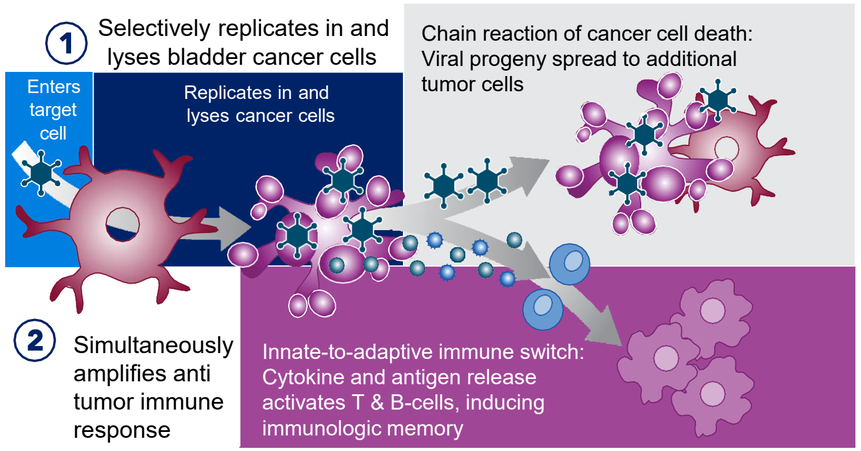
First Patients Treated; Actively Enrolling

Real-World, Expanded Eligibility

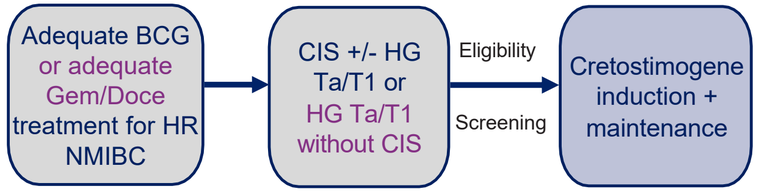
Broad Patient Access Across Community & Academic Sites

ONCOLYTIC IMMUNOTHERAPY

Cretostimogene Grenadenorepvec's Dual Mechanism of Action



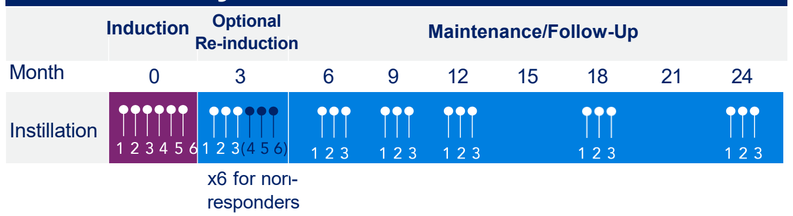
STUDY DESIGN



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 et al, *Lancet Oncol 2026*; **6** U.S. FDA. Expanded Access