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Streamlined, Patient-Centric Design of the Cretostimogene Grenadenorepvec Expanded Access Program in Patients with Non-Muscle Invasive Bladder Cancer Unresponsive to Bacillus Calmette-Guerin

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BACKGROUND

- **Cretostimogene grenadenorepvec is an oncolytic immunotherapy with a dual mechanism of action: it replicates in and lyses cancer cells while amplifying the immune response against bladder tumors**
- **BOND-003 Trial (cretostimogene in BCG-UR NMIBC with CIS) demonstrated a 75% CR 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**
- **An Expanded Access Program (EAP) is a pathway designed to give patients access to potentially beneficial investigational treatments before they are approved [6]**

CRETO-EAP will offer cretostimogene for patients with CIS-containing BCG-unresponsive NMIBC, with the following considerations:

- Ineligible for, or have limited access to, other BCG-UR CIS clinical trials
- Are unable to tolerate available treatment options
- Have limited or restricted access to alternative therapies

Abbreviations: CFS = cystectomy-free survival; CR = complete response; DoR = duration of response; HRQoL = health-related quality of life; NMIBC = non-muscle invasive bladder cancer; PFS = progression-free survival; PRO = patient reported outcomes; UR = unresponsive

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

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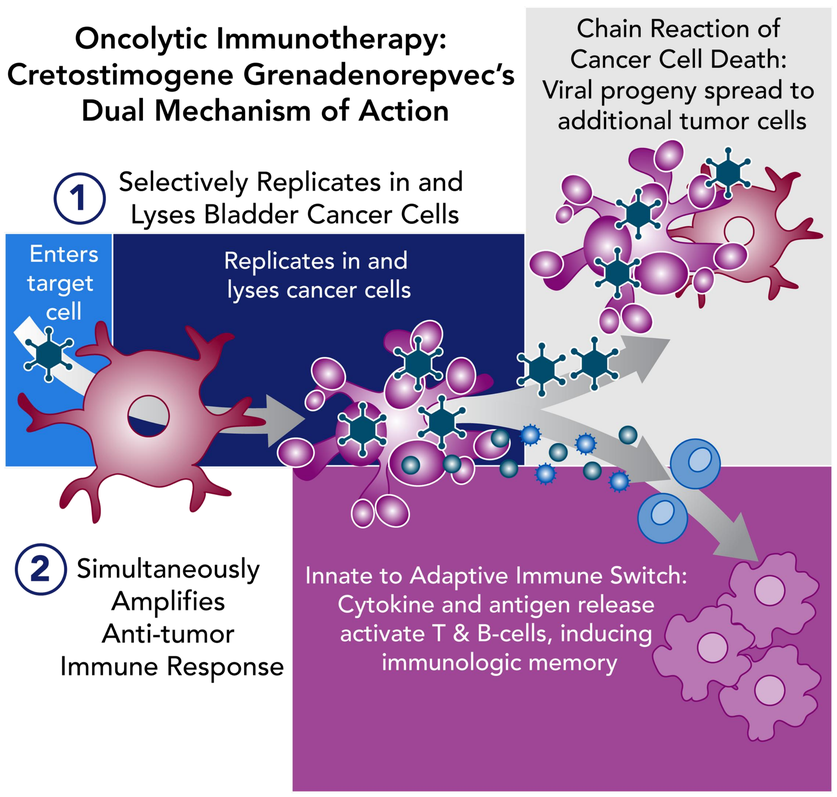
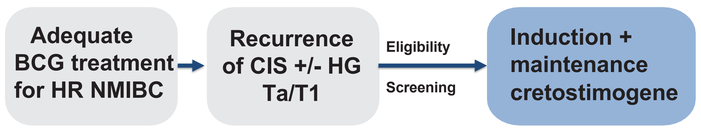
CRETO-EAP EXPANDED ACCESS PROGRAM

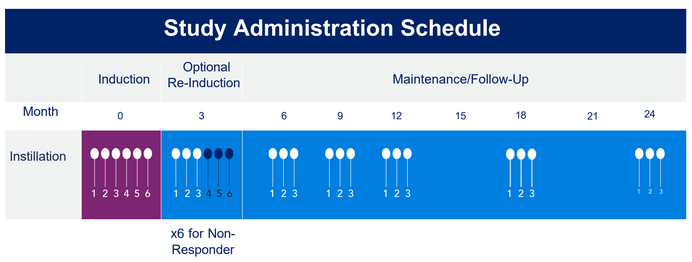
- ✓ First Patients Treated
- ✓ Actively Enrolling
- ✓ Real-World Population
- ✓ Diverse Patients and Sites



STUDY DESIGN



- **Flexible entry criteria: ECOG 0-3, expanded window for prior intravesical BCG, previous investigational therapy permitted, adaptable screening process**
- **Eligibility and efficacy based on local assessments**
- **Co-primary endpoints: Safety & CR at any time**
- **Secondary endpoints: DoR, PFS, CFS, PROs and HRQoL**



- **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 guidelines**

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

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CRETO-EAP
EXPANDED ACCESS PROGRAM

- ***Pathway designed to give patients access to potentially beneficial investigational treatments before they are approved***

- Co-primary endpoints:
  - Safety & CR at any time
- Key Features:
  - Flexible (real-world) entry criteria
  - Reinduction for partial responders
  - Assessments scheduled during routine NMIBC surveillance
- Conclusion:
  - First patients treated
  - Actively enrolling

CRETO-EAP will offer cretostimogene for patients with CIS-containing BCG-unresponsive NMIBC, with the following considerations:

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