

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 selectively replicates in and lyses cancer cells while amplifying the immune response against bladder tumors
- BOND-003 evaluating cretostimogene in BCG-UR NMIBC with CIS population showed 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

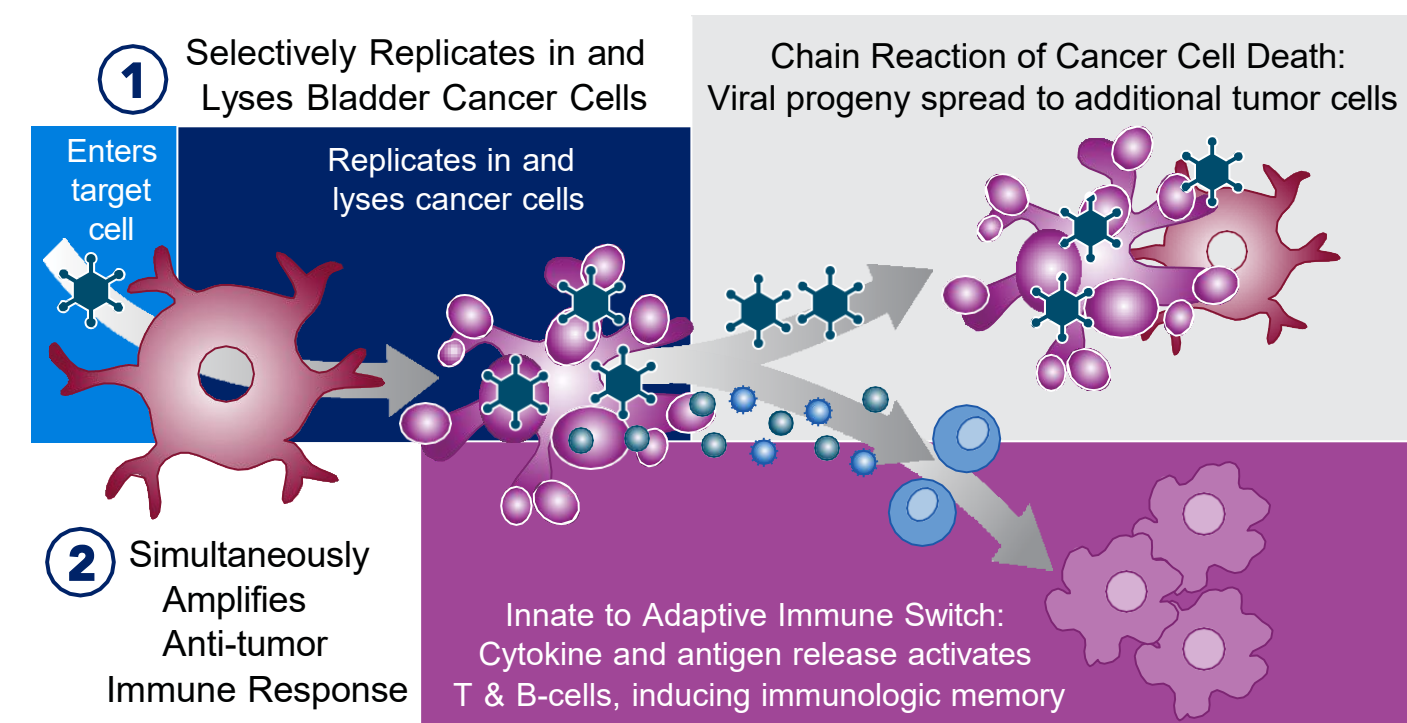
First Patients Treated

Actively Enrolling

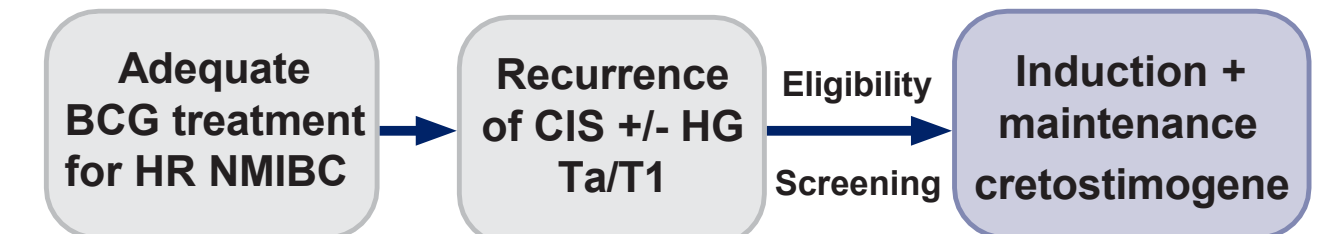
Real-World Population

Diverse Patients and Sites

Oncolytic Immunotherapy: Cretostimogene Grenadenorepvec's Dual Mechanism of Action



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

Study Administration Schedule

	Induction		Optional Re-Induction	Maintenance/Follow-Up					
Month	0	3	6	9	12	15	18	21	24
Instillation	1 2 3 4 5 6	1 2 3 (4 5 6)	1 2 3	1 2 3	1 2 3		1 2 3		1 2 3

x6 for Non-Responder

- 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

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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