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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 a tumor-selective 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 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

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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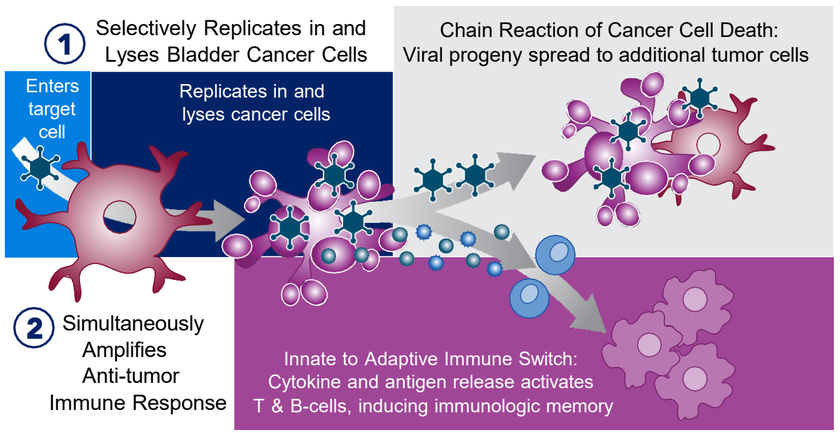
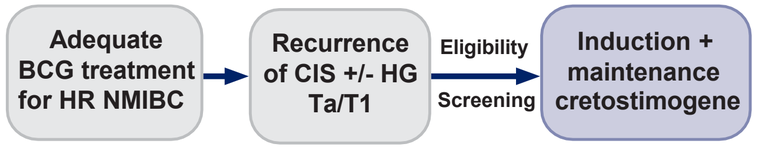
CRETO-EAP
EXPANDED ACCESS PROGRAM

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

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) x6 for Non-Responder	1 2 3	1 2 3	1 2 3		1 2 3		1 2 3

- **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:
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