

# M25 Design & Implementation of a Patient-Centric Expanded Access Program with Cretostimogene Grenadenorepvec in Non-Muscle Invasive Bladder Cancer Unresponsive to Bacillus Calmette-Guerin

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## BACKGROUND

- Cretostimogene grenadenorepvec is an oncolytic immunotherapy with dual mechanisms of action: it selectively replicates in and lyses cancer cells while amplifying the immune response against bladder tumors.
- 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.<sup>1-5</sup>
- 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.<sup>6</sup>

### CRETO-EAP offers 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; TRAE= treatment-related adverse events; 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, SUO Meeting, 2025; 6 U.S. FDA. Expanded Access  
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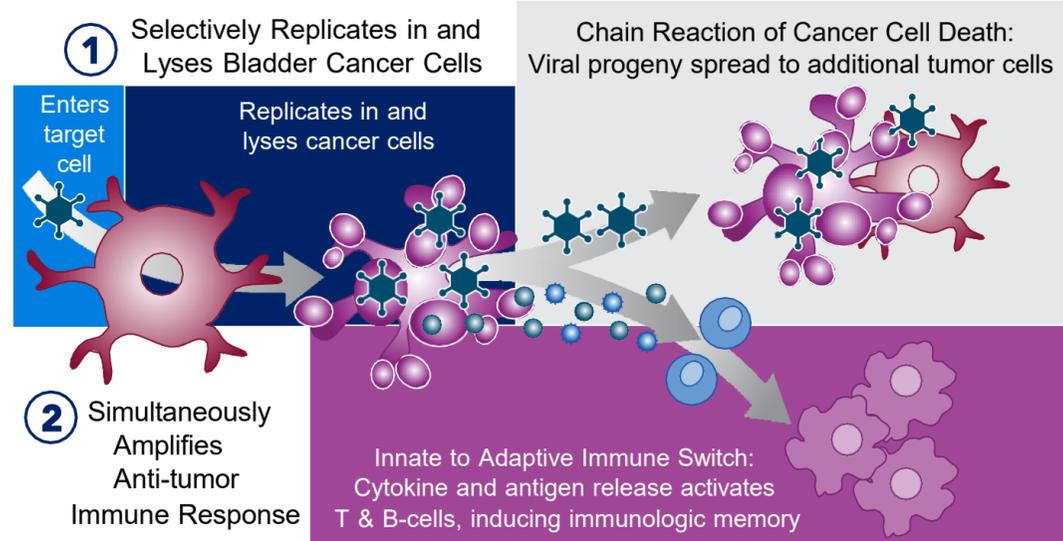
## First Patients Treated

## Actively Enrolling

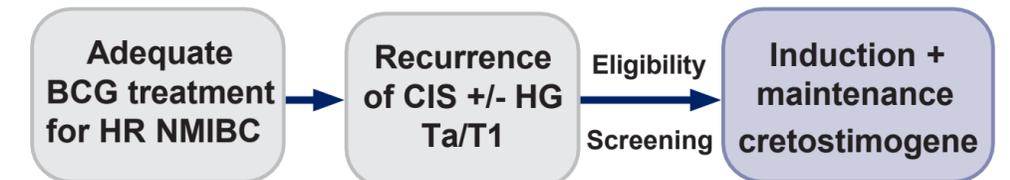
## Real-World Population

## 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/SUO guidelines

**To learn more and how to participate, please contact:**  
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