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Expanded Access Program of Cretostimogene Grenadenorepvec in Patients with High-Risk BCG-Unresponsive NMIBC with CIS

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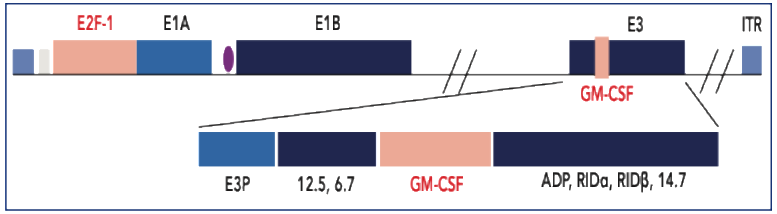
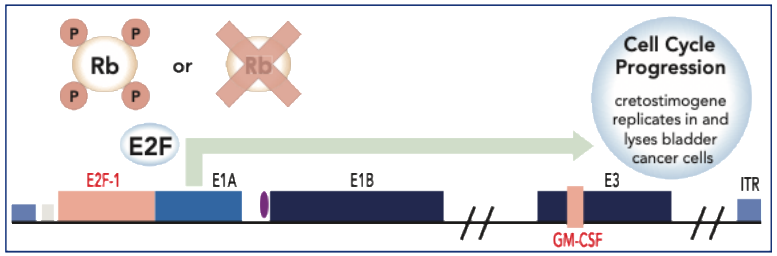
BACKGROUND

- Cretostimogene grenadenorepvec is an oncolytic immunotherapy with a dual mechanism of action
- Selectively replicates in and lyses cancer cells while simultaneously amplifying the immune response against bladder tumors
- Cretostimogene demonstrates Complete Response rates of 46-85% with favorable safety and tolerability in High-Risk NMIBC previously treated with BCG [1-5]
- Granted US FDA Fast Track and Breakthrough Therapy Designations in HR BCG-UR NMIBC CIS +/- HG Ta/T1
- EAP will offer treatment for patients ineligible for, or have limited access to, many BCG-UR CIS clinical trials[6]





References: **1** Burke, *J Urol*; 2012, **2** Packiam, *Uro Onc*; 2018, **3** Li, AUA Meeting; 2022, **4** Tyson, SUO Meeting; 2023, **5** Tyson, AUA Meeting, 2024; **6** U.S. FDA. Expanded Access

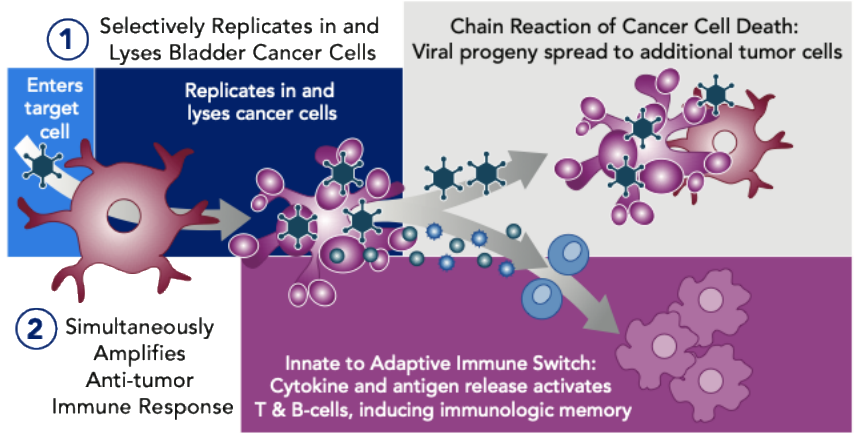
CRETO-EAP
EXPANDED ACCESS PROGRAM

Actively Enrolling

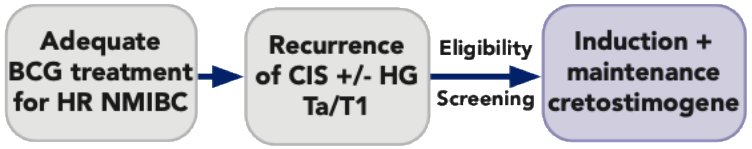
Real-World Population

Diverse Sites Identified

Oncolytic Immunotherapy: Cretostimogene Grenadenorepvec's Dual Mechanism of Action

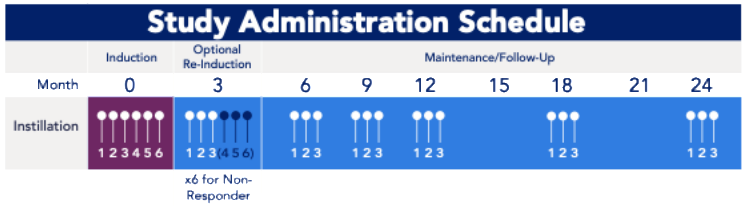


STUDY DESIGN



- Pragmatic entry criteria: ECOG 0-3, extended window for prior intravesical therapy, adaptable screening process
- Eligibility and efficacy based on local assessments
- Co-primary endpoints: Safety & CR at any time
- Secondary endpoints: DoR, PFS, CFS
- Exploratory endpoints: PROs and HRQoL

Study Administration Schedule



Patients will be assessed for response during routine NMIBC surveillance, every 12 weeks during the Treatment Phase according to AUA guidelines.

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