MP-04.31

Updates to a Patient-Centric Expanded Access Program with Cretostimogene Grenadenorepvec for BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

Sarah P. Psutka, MD, MSc;[1] Shane M. Pearce, MD;[2] Aaron Berger, MD;[3] Vikram Narayan, MD; [4] Jeffrey A. Pearl, MD;[5] Yair Lotan, MD;[6] Siamak Daneshmand, MD;[7*] and Anne K. Schuckman, MD[7]

[1] Department of Urology, University of Washington, Seattle, WA; [2] Spokane Urology, Spokane, WA; [3] Associated Urologic Specialists, Chicago Ridge, IL; [4] Department of Urology, Emory University School of Medicine, Atlanta, GA; [5] UroPartners LLC, Schaumburg, IL; [6] Department of Urology, University of Texas Southwestern Medical Center, Dallas, TX; [7] USC Institute of Urology, Norris Comprehensive Cancer Center, University of Southern California, Los Angeles, CA

For individual reference only. The information accessed through this QR code is intended solely for individual reference and should not be altered, modified, or reproduced in any way.

BACKGROUND

- Cretostimogene grenadenorepvec is an oncolytic immunotherapy with dual mechanisms of action (Figure)
- 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.[1-4]
- Granted US FDA Fast Track and Breakthrough Therapy Designations in HR BCG-UR NMIBC CIS +/- Ta/T1.
- Expanded Access Programs (EAP) are designed to give patients access to potentially beneficial investigational treatments before they are approved.[5]

CRETO-EAP offers cretostimogene for patients with BCG-unresponsive NMIBC with the following considerations

- Ineligible for, or limited access to, other BCG-UR clinical trials
- Unable to tolerate available treatment options
- Limited or restricted access to alternative therapies

Initial Population

- Pathologically confirmed BCG-unresponsive CIS ± HG Ta/T1 NMIBC
- Expanded window for prior intravesical therapy

2026 Protocol Amendment

- Expanded eligibility for patients with BCG-unresponsive HG Ta/T1 NMIBC without CIS
- Patients who are unable to access BCG and who received adequate Gem/Doce may be eligible upon recurrence

Abbreviations: Creto-EAP: Cretostimogene Expanded Access Program; NMIBC: Non-Muscle-Invasive Bladder Cancer; CIS: carcinoma in situ; HR: high-risk; HG: high-grade; DoR: Duration of Response; EFS: event-free survival; TRAEs: Treatment-Related Adverse Events; Gem/Doce: Gemcitabine/Docetaxel

CRETO-EAP

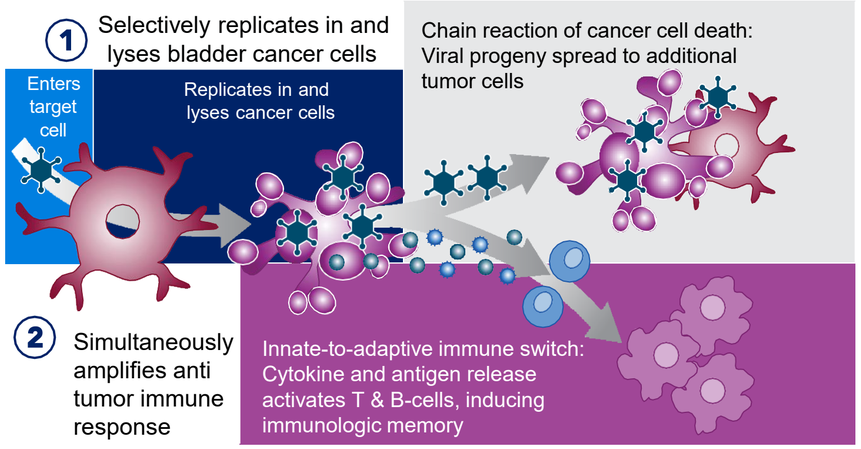
First Patients Treated; Actively Enrolling

Real-World, Expanded Eligibility

Broad Patient Access Across Community & Academic Sites

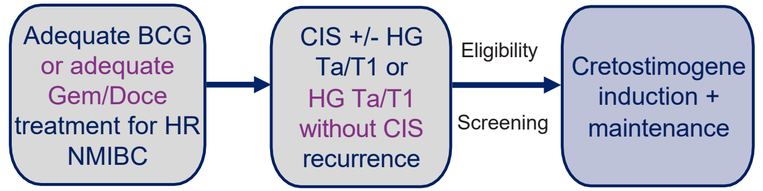
ONCOLYTIC IMMUNOTHERAPY

Figure 1. Cretostimogene Grenadenorepvec's Dual Mechanism of Action



Contact : Siamak Daneshmand: daneshma@med.usc.edu

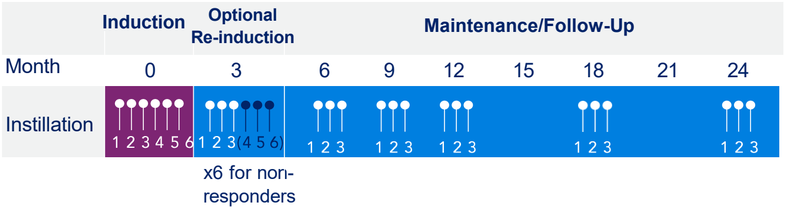
Figure 2. Study Design



Purple text indicates protocol amendments

- Eligibility and efficacy based on local assessments
- Primary endpoint: Safety
- Co-secondary endpoints: CR at any time (CIS-containing disease); HG-EFS (HG Ta/T1; papillary-only)

Figure 3. Study Administration Schedule



- Patients with partial response at Month 6 or later, who may still be deriving clinical benefit without meeting strict CR criteria, may continue treatment at the Investigator's discretion
- Patients will be assessed for response during routine NMIBC surveillance, according to AUA/SUO guidelines

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

Acknowledgements: Pat Keegan, MD, MPH; Rob Svatek, MD; Leah Rider, PhD; My Nguyen, MHA; Shawna Ruffin; Shelja Patel, PharmD; Sarah Hohl, PhD; & Vijay Kasturi, MD

References: **1** Burke, *J Urol*; 2012, **2** Packiam, *Urol Oncol*; 2018, **3** Tyson et al. 2026, Lancet Oncology. **4** Li, *Nat Med*; 2024, **5** U.S. FDA. Expanded Access