Integrating Cretostimogene Grenadenorepvec in Urology Practices: Clinical and Practical Nursing Considerations from the BOND-003 Study

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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 (NCT04452591) is a pivotal phase 3 trial designed to evaluate cretostimogene in patients with HR BCG-UR NMIBC
- We present practical considerations with the use of cretostimogene

BOND-003 STUDY DESIGN & RESULTS

- Enrolled 112 patients with HR BCG-UR NMIBC with CIS +/- Ta/T1
- Familiar intravesical treatment schedule
- Response assessments: cystoscopy (± biopsy) & cytology q3mo
 × 2yrs, then q6mo starting Yr 3; all responses centrally confirmed

Study Administration Schedule Induction Maintenance/Follow-Up Re-Induction 21 12 15 18 24 123 123 123 123 Mandatory Extended x6 for Non-Responder Maintenance **Biopsy**

- CR rate at any time is 75.5% (83/110) (95% CI 66.3-83.2%)
- Median DOR is 27.9 months (95% CI 14.3-NE%) and is on-going
- At 24 months 97.3% were free from progression to <u>></u>T2 disease and 84.5% avoided RC
- Most AEs were grade 1-2; 1-day median time to TRAE resolution

100	Overall Complete Response 75.5% (95% CI, 66.3 % - 83.2 %)	CR Landmark	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
verall CR Rate (%)		12-month	46.4% (36.9, 56.1) 51 out of 110 patients	50.7% (40.9, 59.8)
Overall C	CR (n=83)	24-month	41.8% (32.5, 51.6) 46 out of 110 patients	42.4% (32.7, 51.7)
•	(n=110)			

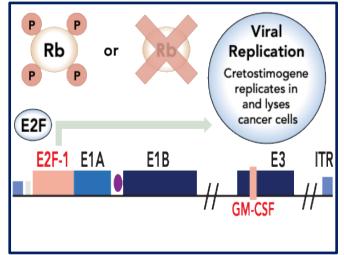
Preferred Term	Cretostimogene (n=112)		
(MedDRA v.26.1)	Any Grade (%)	Grade <u>≥</u> 3	
Patients with ≥1 TRAE	71 (63.4%)	0 (0)	
Treatmo	ent-Related AE reported in >20% p	patients	
Bladder Spasm	28 (25%)	0 (0)	
Pollakiuria	24 (21.4%)	0 (0)	
Urgency	23 (20.5%)	0 (0)	

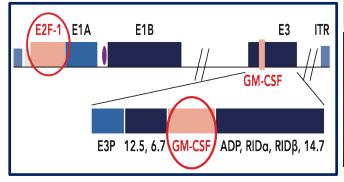




- Cretostimogene is an effective, well-tolerated intravesical therapy that integrates safely and efficiently into urology workflow
- Cretostimogene is currently under investigation for Intermediate- and high-risk NMIBC
- Nurses and APPs play a vital role integrating novel bladder cancer therapies and enhancing patient experience

Cretostimogene in cancer cells





Nurse, Medical Assistant*, Nurse Practitioner, Physician Assistant, Urologist

Preparation & Administration

May be completed in a standard clinic room



creto dwell



* Subject to state laws and institutional policies

KEY NURSING CONSIDERATIONS

Pre-Instillation Planning

- Review patient history (difficult catheterizations, UTI, etc)
- Gather necessary supplies
- Ensure bladder is emptied prior to instillation
- No Pretreatment or ancillary medications are required per protocol

Preparation & Handling

- Ensure DDM (excipient) and creto are completely thawed before use
- Follow universal biosafety protocols- cretostimogene is BSL-2 like BCG
- Use appropriate protective equipment (e.g., gloves, gown, eye protection) during preparation and administration

Administration

- Convenient in-office instillation with familiar treatment schedule
- Aligned with joint AUA/SUNA policy & position statement on IVE therapy
- Administered with foley (indwelling with balloon)
- Administration allows patient throughput and comfort

Follow-Up & Patient Education

- Provide instructions and resources for post treatment care
- Close contact with loved ones is acceptable if patient is free from coldor flu-like symptoms
- Counsel on the importance of open communication with the care team regarding potential side effects
- Reinforce importance of ongoing NMIBC surveillance and adherence to the treatment plan

Abbreviations: BSL= Bio Safety Level 2; CIS = carcinoma in situ; CR = complete response; DOR = duration of response; IVE= Intravesical; K-M = Kaplan-Meier; NMIBC = non-muscle invasive bladder cancer; TRAE= Treatment-related adverse event; UR = unresponsive

Acknowledgements: Andy Darilek, MD; Jee-Hyun Kim, PhD; Pat Keegan, MD; Robert Svatek, MD, MSCI; Rebecca Tregunna, MD, MBA; Shelja Patel, PharmD and Vijay Kasturi, MD