#352

# Topline Results From BOND-003 Cohort P- A Multi-National, Single-Arm Study of Intravesical Cretostimogene Grenadenorepvec for Treatment of High-Risk BCG-Unresponsive NMIBC with HG Ta/T1 (Without CIS)

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.

**Siamak Daneshmand, MD;[1] Mark D. Tyson, MD, MPH;[2] Paras H. Shah, MD;[3] Timothy D. Lyon, MD;[4] Ankeet M. Shah, MD;[5] Thomas J. Guzzo, MD, MPH;[6] Amy N. Luckenbaugh, MD;[7] Rian J. Dickstein, MD;[8] Woodson W. Smelser, MD;[9] Daniel E. Zainfeld, MD;[10] and Colin P. N. Dinney, MD[11]**

[1] Keck School of Medicine of USC, Los Angeles, CA; [2] Mayo Clinic, Phoenix, AZ; [3] Mayo Clinic, Rochester, MN; [4] Mayo Clinic, Jacksonville, FL; [5] Duke University School of Medicine, Durham, NC; [6] Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA; [7] Vanderbilt University Medical Center, Nashville, TN; [8] Chesapeake Urology Associates, Hanover, MD; [9] Washington University School of Medicine, St. Louis, MO; [10] UT Health San Antonio, San Antonio, TX; [11] University of Rochester Medical Center, Rochester, NY

## BACKGROUND

- BCG-UR papillary-only population comprises the majority of BCG-UR NMIBC patients [1]
- US FDA approved treatments for high-risk (HR) BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) exist[2]
- Additional bladder-sparing therapies are needed, especially for the BCG-Unresponsive HG Ta/T1 population[3]
- 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 Cohort P evaluates cretostimogene in patients with HR BCG-UR with HG Ta/T1 (papillary-only)

## METHODS

- Enrolled patients with HG Ta/T1 without CIS
- BCG-Unresponsive defined as recurrent HG Ta/T1 within 6 months of last adequate BCG dose per FDA guidance
- HG T1 after single BCG induction course may be eligible
- Response assessments include cystoscopy (biopsy as indicated) & cytology every 3 months for first 2 years and every 6 months starting Year 3

### Study Administration Schedule

| | Induction | Optional Reinduction | Maintenance/Follow-Up | | | | | | Ext. Maintenance/ Long-Term Follow-up |
|---|---|---|---|---|---|---|---|---|---|
| Month | 0 | 3 | 6 | 9 | 12 | 15 | 18 | 21 | 24/30/36 |
| 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-Responders

Mandatory Biopsy

## RESULTS

### Baseline characteristics

| Patients in Safety Dataset | N=56 | % |
|---|---|---|
| **Gender** | | |
| Male | 44 | 78.6 |
| Female | 12 | 21.4 |
| **Age (Years)** | | |
| Median (Range) | 74.0 | (45-87) |
| **Age (Categories)** | | |
| < 65 | 13 | 23.2 |
| ≥ 65 and < 75 | 18 | 32.1 |
| ≥75 | 25 | 44.6 |
| **HR NMIBC T-Stage at Study Entry** | | |
| HG Ta | 33 | 58.9 |
| HG T1 | 23 | 41.1 |
| **BCG History: No. of Prior Instillations** | | |
| Median (Range) | 9.0 | (5 – 21) |

**Abbreviations:** BCG: Bacillus Calmette-Guerin; CIS: carcinoma in situ; CR: complete response; EFS: event-free survival; HG: high-grade; HR: high-risk; MIBC: muscle-invasive bladder cancer; NMIBC: non-muscle invasive bladder cancer; RC: radical cystectomy; TRAE: treatment-related adverse event; UR: unresponsive

**References: 1** NCCN Bladder Cancer Guidelines; 2026, **2** AUA/SUO NMIBC Guidelines; 2026; **3** Remalda Therapeutics, Inc. Press Release, Jan 12, 2026

BOND-003 COHORT P

BCAN 20 Years of Impact

**BCG-UR Papillary-Only NMIBC**

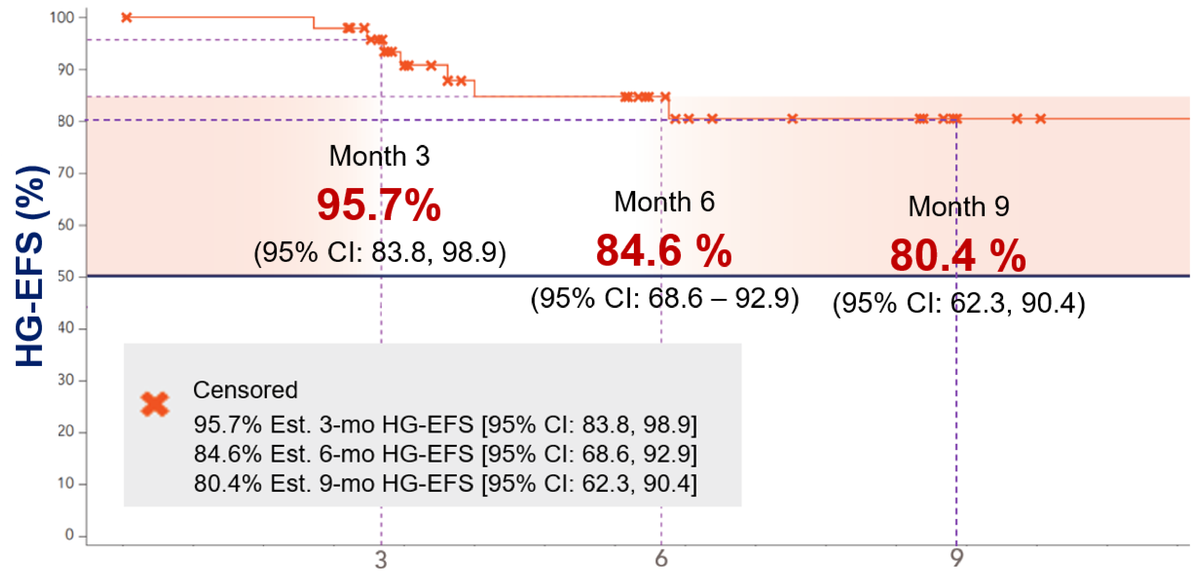
**Consistent, High HG-EFS**

**Well-Tolerated Safety Profile**

**Long-Term Treatment Ongoing**

## TOPLINE RESULTS

### Kaplan-Meier Estimate for HG-EFS




**Months From First Treatment or Re-Induction**

- At median follow-up 6 months, 51 patients are efficacy evaluable
- Strong responses with 95.7%, 84.6%, and 80.4% HG-EFS at 3, 6, and 9 Months, respectively
- Consistent and high HG-EFS:
  - HG Ta: (92.8% (3 mo); 75.9% (6 mo); 75.9% (9 mo)
  - HG T1: (100% (3 mo); 100% (6 mo); 87.5% (9 mo)
- Total 8 patients received re-induction
- No patients underwent RC and no progression to MIBC

### Safety Profile

- 0% Grade ≥ 3 TRAEs, serious TRAE, deaths
- No dose delays, missed doses or discontinuations due to TRAEs
- 98.2% of patients received all protocol-defined treatments

## CONCLUSIONS

- Results demonstrate intravesical cretostimogene's consistent efficacy and well-tolerated safety profile for patients with HR BCG-unresponsive NMIBC with HG Ta/T1
- Mature data with longer term follow-up will build upon these promising findings and will inform future treatment approaches with cretostimogene

**Contact Information**: Siamak Daneshmand, MD: daneshma@med.usc.edu

**Acknowledgements:** Pat Keegan, MD; Jee-Hyun Kim, PhD; Leah Rider, PhD; Anastasiia Shermolovych, MPharm; Angelica Craighead, CCRP; Shelja Patel, PharmD, Sarah D. Hohl, PhD, and Vijay Kasturi, MD

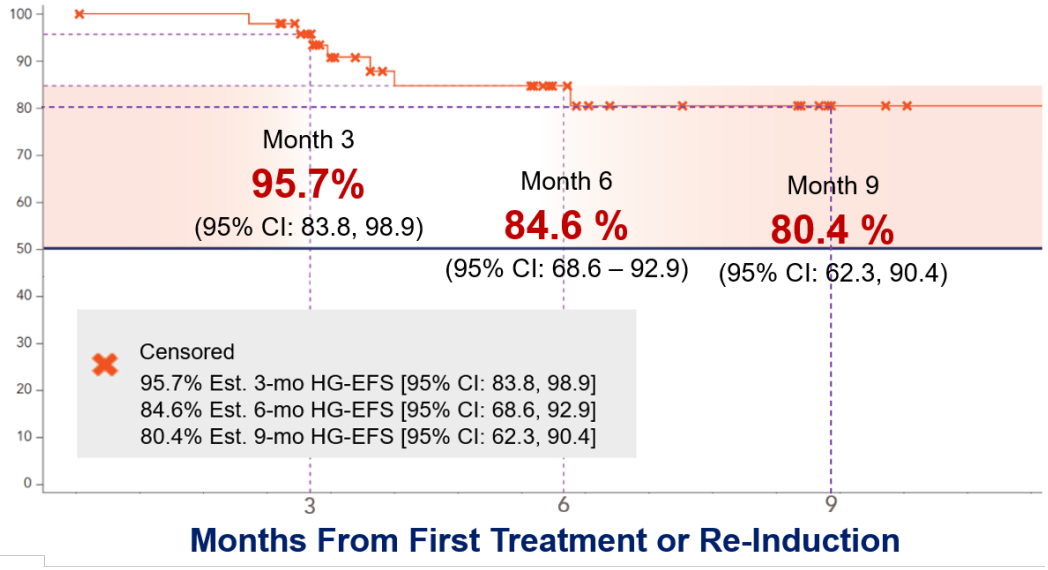
# #352 Topline Results From BOND-003 Cohort P Intravesical Cretostimogene Grenadenorepvec for Treatment of High-Risk BCG-Unresponsive NMIBC with HG Ta/T1 without CIS

- Multi-national, single arm trial
- Patients with pathologically confirmed BCG-UR HG Ta/T1 without CIS
- Primary endpoint: HG-EFS
- Strong responses with 95.7%, 84.6%, and 80.4% HG-EFS at 3, 6, and 9 months, respectively
- Consistent and high HG-EFS

| HG-Ta: | HG-T1: |
|---|---|
| • 92.8% (3 mo) | • 100% (3 mo) |
| • 75.9% (6 mo) | • 100% (6 mo) |
| • 75.9% (9 mo) | • 87.5% (9 mo) |

- 0% Grade ≥ 3 TRAEs, serious TRAE, deaths

## Kaplan-Meier Estimate for High-Grade Event-Free Survival (%)




01Sept2025 data cut off

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.

USC Department of Urology