

G07 Topline Results From BOND-003 Cohort P: A Multi-National, Single-Arm Study of Intravesical Cretostimogene Grenadenorepvec for Treatment of High-Risk, Papillary Only, BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

Siamak Daneshmand, MD;^{1*} Paras H. Shah, MD;² Timothy D. Lyon, MD;³ Ankeet M. Shah, MD;⁴ Trinity J. Bivalacqua, MD, PhD;⁵ Amy N. Luckenbaugh, MD;⁶ Colin P. Dinney, MD⁷ & Mark D. Tyson, MD, MPH⁸

¹ University of Southern California, Los Angeles, California ² Mayo Clinic, Rochester, Minnesota ³ Mayo Clinic, Jacksonville, Florida ⁴ Duke University Medical Center, Durham, North Carolina ⁵ University of Pennsylvania, Philadelphia, Pennsylvania ⁶ Vanderbilt University, Nashville, Tennessee ⁷ University of Rochester, Rochester, New York ⁸ Mayo Clinic, Phoenix, Arizona



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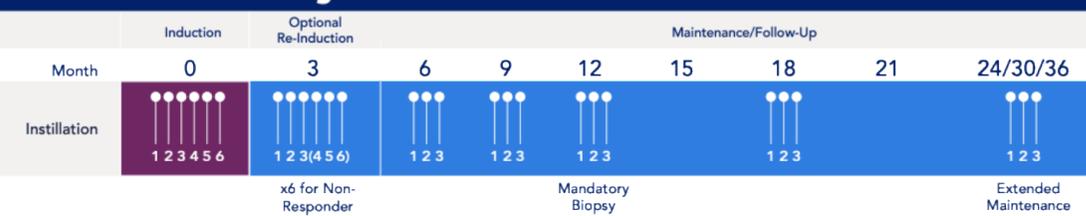
BACKGROUND

- BCG-UR papillary-only population comprises the majority of BCG-UR NMIBC patients ¹
- Current FDA approved therapies are indicated for CIS containing HR BCG-UR NMIBC and none are approved for BCG-UR papillary-only NMIBC ²
- With existing therapies offering modest benefit for BCG-UR papillary-only NMIBC, there exists a significant unmet need 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)

STUDY DESIGN

- 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



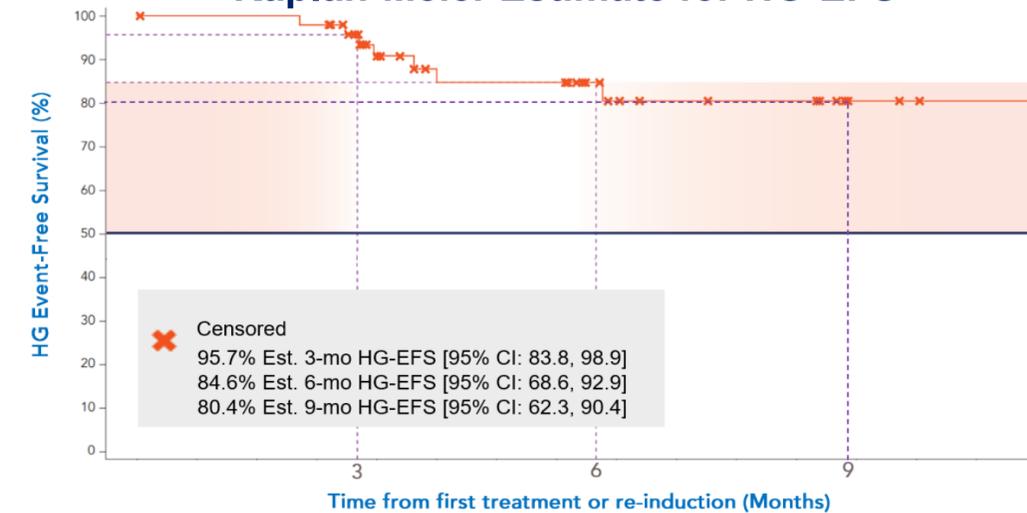
BCG-UR Papillary-Only NMIBC
Consistent, High HG-EFS
Well-Tolerated Safety Profile
Long-Term Treatment Ongoing

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)	

TOPLINE RESULTS

Kaplan-Meier Estimate for HG-EFS



- 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 in HG Ta and HG T1
- 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% received protocol defined treatments

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 Global Cancer Statistics; 2019, 2 Musat, *CEOR*; 2022, 3 Rose, *Soc Int Urol J.*; 2022
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Contact Information: Siamak Daneshmand, MD; daneshma@med.usc.edu