IP-04.13

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

Trinity J. Bivalacqua, MD, PhD;[1] Aaron Berger, MD;[2] Mark D. Tyson, MD, MPH;[3] Christopher M. Pieczonka, MD;[4] Kyle Rose, MD;[5] Gary D. Steinberg, MD;[6] Siamak Daneshmand, MD;[7*] and Colin P. N. Dinney, MD [8]

[1]Department of Urology, University of Pennsylvania, Philadelphia, PA; [2]Associated Urological Specialists, Chicago Ridge, IL; [3]Department of Urology, Mayo Clinic, Phoenix, AZ; [4]Associated Medical Professionals of New York Syracuse, NY; [5]Ochsner Medical Center, New Orleans, LA; [6]GDS Consulting, Chicago, IL; [7]University of Southern California/Norris Comprehensive Cancer Center, Los Angeles, CA; [8]Department of Urology, University of Rochester, Rochester, NY

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.

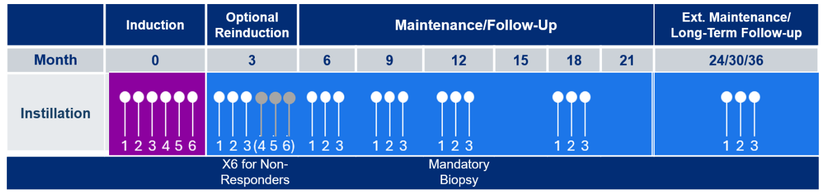
BACKGROUND

- BCG-UR papillary-only population comprises the majority of BCG-UR NMIBC patients [1]
- FDA-approved treatment options for BCG-UR HG Ta/T1 (papillary-only) NMIBC remain limited compared CIS-containing disease.
- With limited available treatment options for Ta/T1 (papillary-only) disease, there exists a significant unmet need [3]
- 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 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-UR 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 & cytology every 3 months for first 2 years and every 6 months starting Year 3, biopsy at 12 months

Figure 1. Study Administration Schedule



Acknowledgements: Jee-Hyun Kim, PhD; Pat Keegan, MD; Rob Svatek, MD; Leah Rider, PhD; Anastasiia Shermolovych, M.Pharm; Shelja Patel, PharmD, Sarah Hohl, PhD and Vijay Kasturi, MD

BOND-003 COHORT P

BCAN 20 Years of Impact

BCG-UR Papillary-Only NMIBC
Robust High HG-EFS Across Clinical Program
Strong Safety Profile
Long-Term Treatment Ongoing

RESULTS

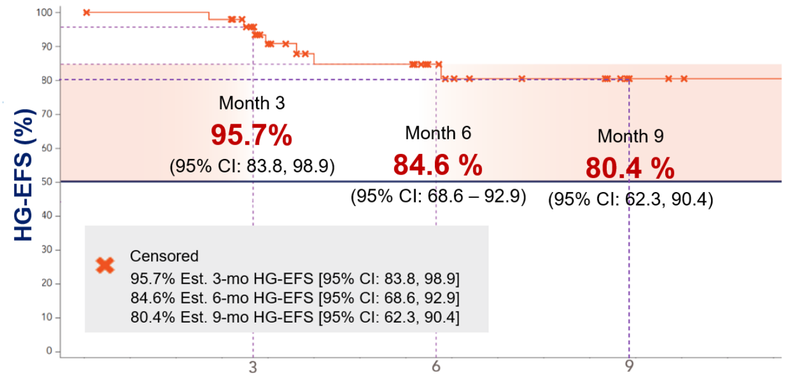
Baseline characteristics

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	37	66.1
HG T1	19	33.9
BCG History: No. of Prior Instillations		
Median (Range)	9.0	(5 – 21)

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

References: **1** Global Cancer Statistics; 2019, 2 Rose, Soc *Int Urol J.;* 2022

Figure 2. 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 HG-EFS in HG Ta and HG T1

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)

- 11 patients received re-induction
- No patients underwent RC; no progression to MIBC

Safety Profile

- No grade ≥ 3 TRAEs, serious TRAE, deaths
- No dose delays, missed doses, or discontinuations due to TRAEs
- 98.2% of patients received protocol defined treatments
- Safety profile matched what has been seen across the cretostimogene clinical program; the selective mechanism of action may help limit off-target AEs

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