Trial in Progress: 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

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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 (CR of 25% at 12 months), 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
- Granted US FDA Fast Track and Breakthrough Therapy Designations in HR BCG-UR NMIBC CIS +/- Ta/T1

To address this unmet need, BOND-003 Cohort P studies adjuvant cretostimogene in patients with papillary-only, BCG-UR NMIBC

Abbreviations: BCG = Bacillus Calmette-Guerin; CIS = carcinoma in situ; CR = complete response; EFS= event-free survival; HG = high-grade; HR = high-risk; NMIBC = non-muscle invasive bladder cancer; 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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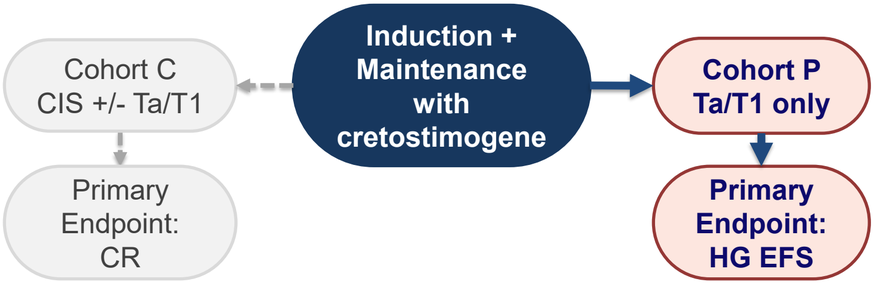
BOND-003 COHORT P

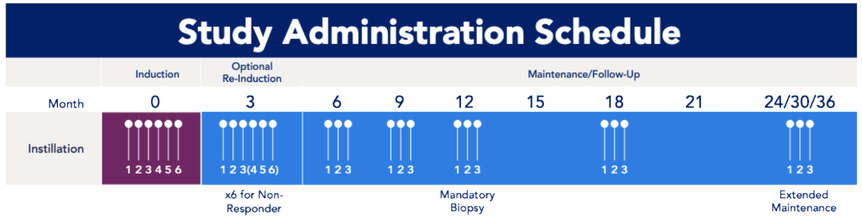
BCAN 20 Years of Impact

BCG-UR Papillary-Only NMIBC
Completed Enrollment
First Results Shared
35+ Sites Globally

BOND-003: High-Risk BCG-Unresponsive NMIBC



Study Administration Schedule



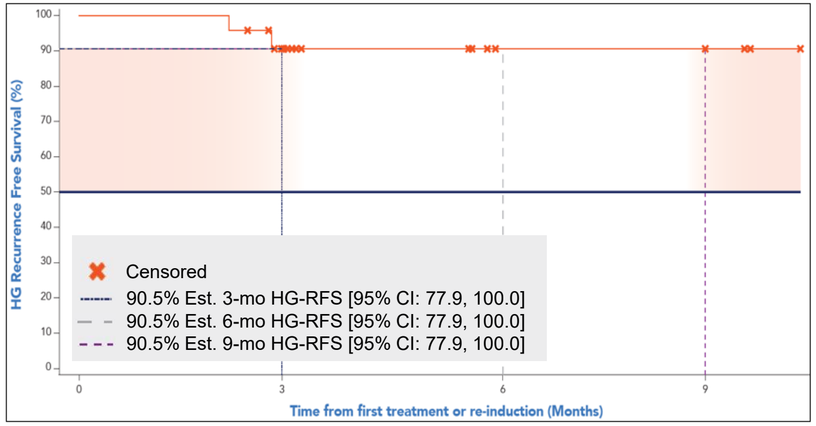
STUDY DESIGN

- 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

INITIAL RESULTS

- Strong, early response with 90.5% HG-RFS (95% CI: 77.9-100%) at 3 and 9 Months for first 24 treated patients
- Very well-tolerated regimen with no serious TRAEs

Kaplan-Meier Estimate for High Grade Recurrence-Free Survival



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