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Final Results from BOND-003 Cohort C: A Phase 3, Single-Arm Study of Intravesical Cretostimogene Grenadenorepvec for High-Risk BCG-Unresponsive Non-Muscle Invasive Bladder Cancer with Carcinoma In Situ

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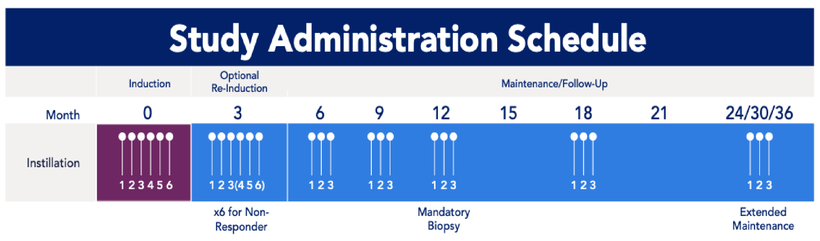
BACKGROUND

- **Considerable unmet need exists for effective, well-tolerated bladder-sparing treatment options for patients with HR BCG-UR NMIBC with CIS[1]**
- **BCG-UR defined as persistent or recurrent CIS +/- Ta/T1 within 12 months of BCG therapy per FDA guidance[2]**
- **Cretostimogene grenadenorepvec is an oncolytic immunotherapy with a dual mechanism of action; it 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**
- **BOND-003 is a pivotal phase 3 trial designed to evaluate cretostimogene in patients with BCG-UR NMIBC**

METHODS

- **Enrolled 112 patients with HR BCG-UR NMIBC with CIS +/- Ta/T1**
- **All visible disease was resected prior to treatment**
- **Response assessments include cystoscopy (biopsy as indicated) & cytology every 3 months for first 2 years and every 6 months starting Year 3; all responses are centrally confirmed**

Study Administration Schedule



Abbreviations: CIS = carcinoma in situ; CR = complete response; DOR = duration of response; K-M = Kaplan-Meier; NMIBC = non-muscle invasive bladder cancer; UR = unresponsive

References: 1 NCCN Bladder Cancer Guidelines; 2025, **2** FDA Guidance; 2024

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BOND-003 COHORT C

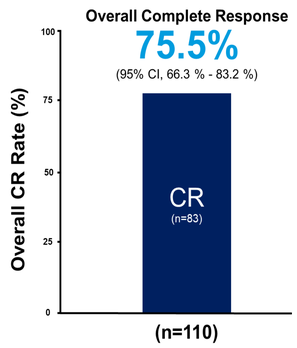
BCG-UR NMIBC with CIS Trial

- ✓ 75.5% Overall CR
- ✓ Median DOR 27.9 Months & Ongoing
- ✓ 0% Grade ≥3 TRAEs

BCAN 20 Years of Impact

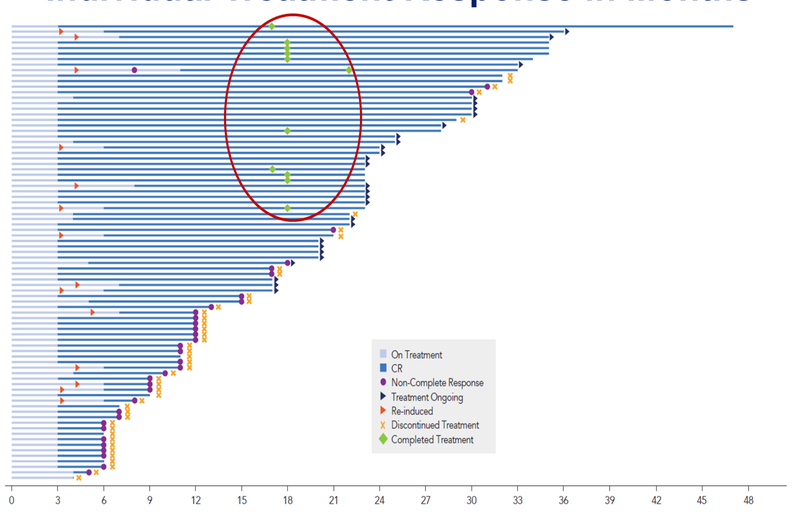
RESULTS

- **Majority of patients are male (74%), white (62%) & > 65 years old (83%)**
- **With a median follow-up time of 22.3 months, 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% (107/110) were ≥T2 progression free and 84.5% (93/110) avoided radical cystectomy**
- **Most AEs were grade 1-2; 1-day median time to resolution**

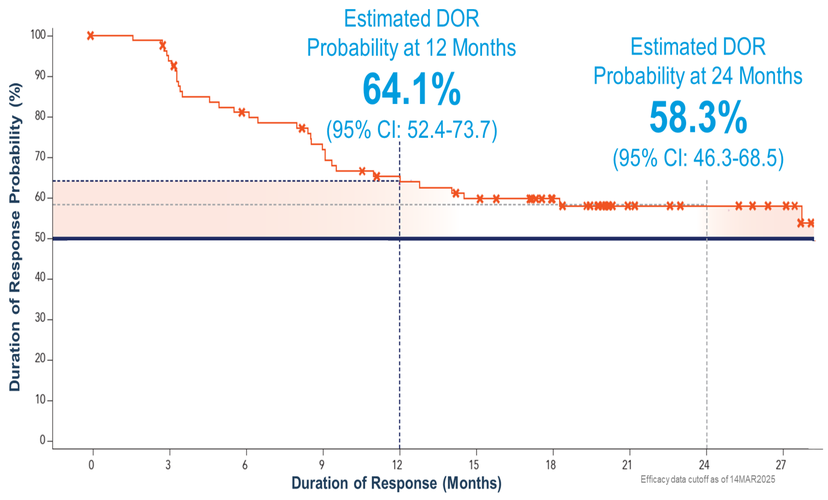


CR Landmark	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
12-month	**46.4%** (36.9, 56.1) *51 out of 110 patients*	**50.7%** (40.9, 59.8)
24-month	**41.8%** (32.5, 51.6) *46 out of 110 patients*	**42.3%** (32.7, 51.6)

Individual Treatment Response in Months



Duration of Response



Safety Profile

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

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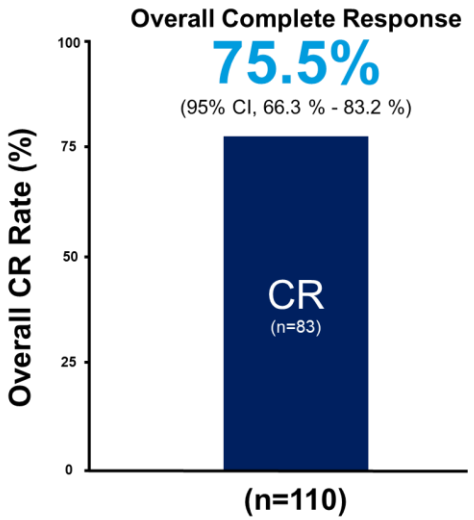
- **Population:** HR BCG-UR CIS ± Ta/T1; n=112 enrolled
- **Design:** Phase 3, Single-arm trial
- **Treatment:** intravesical cretostimogene, an oncolytic immunotherapy with dual mechanism of action
  - Schedule: weekly x 6 followed by maintenance; re-induction permitted
- **Efficacy:** CR at any time 75.5% (83/110); median DOR 27.9 mo & ongoing
- **Safety:** 0% Grade ≥3 TRAEs; most AEs Grade 1–2 with ~1-day median time to TRAE resolution
- **Conclusion:** Cretostimogene offers distinct advantages with its efficacy, durability and safety profile for the treatment of HR BCG-UR NMIBC



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