

Cystectomy-Free Survival Following Cretostimogene Grenadenorepvec in High-Risk BCG-Unresponsive Non-Muscle Invasive Bladder Cancer with Carcinoma In Situ: Results from the Phase 3 BOND-003 Trial (Cohort C)

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BACKGROUND

- Radical cystectomy remains the guideline-recommended treatment for HR BCG-UR NMIBC, though effective in controlling disease, it carries substantial morbidity and complications^{1,2}
- Considerable unmet need exists for effective, well-tolerated bladder-sparing treatment options for patients with HR BCG-UR NMIBC with CIS¹
- 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 is a pivotal Phase 3 trial designed to evaluate cretostimogene in patients with BCG-UR NMIBC
- We report outcomes from cystectomies performed on Cohort C

METHODS

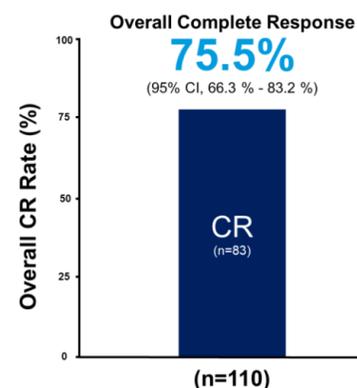
- Enrolled 112 patients with HR BCG-UR NMIBC with CIS +/- Ta/T1
- All visible disease was resected prior to treatment
- Response assessments include cystoscopy (biopsy as indicated) & cytology every 3 months for first 2 years and every 6 months starting Year 3; all responses are centrally confirmed
- CFS calculated from first study treatment to cystectomy or censoring, whichever occurred first in the efficacy analysis set



Strong, Durable Responses
Most Patients Avoided Cystectomy
Preserved Window of Opportunity
Well-Tolerated Safety Profile

RESULTS

- Majority of patients are male (74%), white (62%) & >65 years old (83%)
- With a median follow-up time of 25.8 months, CR rate at any time is 75.5% (83/110) (95% CI 66.3-83.2%)
- High landmark CR at 12 and 24 mo of 46.4% (51/110) and 41.8% (46/110)
- Median DOR is 27.9 months (95% CI 14.3-NE%) and is on-going
- 96.4% (106/110) were free from progression to ≥T2 disease



CR Landmark	CR Rate, % (95% CI)	CR by K-M Est, % (95% CI)
12-month	46.4% (36.8, 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	42.4% (32.7, 51.7)

Cystectomy-Free Survival

- Median CFS not reached in the efficacy analysis set or any subgroups
- 12-month CFS: 89.2% (95% CI 81.3-93.9)
- 24-month CFS: 81.3% (71.8-87.8)

Cystectomy Performed Post-Disease Recurrence or Progression

	Total (n=110)
Patients undergoing a cystectomy post recurrence or progression, n (%)	
Anytime after first recurrence	18 (16.4%)
Within the first year of recurrence	17 (15.5%)
Time to cystectomy post recurrence or progression (weeks)	
Median (Q1, Q3)	20.0 (14.4, 26.7)
Stage at cystectomy, n (%)	
T0	1 (0.9)
CIS	9 (8.2)
HG Ta	1 (0.9)
T1	4 (3.6)
T2A	1 (0.9)
T2B	1 (0.9)
N2	1 (0.9)

- 18 patients underwent RC post-disease recurrence (n=12) or progression (n=6)
- 1 additional patient had RC for UTUC
- 15/18 (83.3%) had NMIBC or pT0 at final pathology

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	25 (22.3%)	0 (0)
Urgency	23 (20.5%)	0 (0)

- Most AEs were Grade 1-2; 1-day median time to TRAE resolution
- High Tx Compliance- no tx-related discontinuations; few missed (1.8%) or delayed (7.1%) doses

Abbreviations: CIS = carcinoma in situ; CFS= cystectomy-free survival; CR = complete response; DOR = duration of response; ITT= intention to treat; K-M = Kaplan-Meier; NMIBC = non-muscle invasive bladder cancer; UR = unresponsive
References: 1 NCCN Bladder Cancer Guidelines; 2025, 2 AUA/SUO NMIBC Guidelines; 2024
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