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Topline Results From BOND-003 Cohort P- A Multi-National, Single-Arm Study of Intravesical Cretostimogene Grenadenorepvec for Treatment of High-Risk BCG-Unresponsive NMIBC with HG Ta/T1 (Without CIS)

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BACKGROUND

- BCG-UR papillary-only population comprises the majority of BCG-UR NMIBC patients [1]
- US FDA approved treatments for high-risk (HR) BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) exist[2]
- Additional bladder-sparing therapies are needed, especially for the BCG-Unresponsive HG Ta/T1 population[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

	Induction	Optional Reinduction	Maintenance/Follow-Up						Ext. Maintenance/ Long-Term Follow-up
Month	0	3	6	9	12	15	18	21	24/30/36
Instillation	1 2 3 4 5 6	1 2 3(4 5 6)	1 2 3	1 2 3	1 2 3		1 2 3		1 2 3

X6 for Non-Responders

Mandatory Biopsy

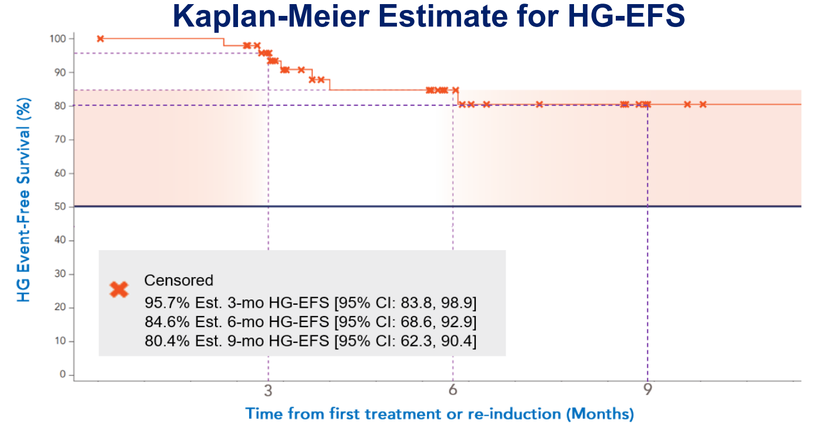
BOND-003 COHORT P

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

BASELINE CHARACTERISITCS

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



- 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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BOND-003 Cohort P- HR BCG-UR Papillary Only (HG Ta/T1) NMIBC

Cohort C (N=112):

- Age ≥ 18 yo
- ECOG PS 0-2
- Pathologically confirmed BCG-UR HR-NMIBC with CIS +/- papillary disease

Primary Endpoint
CR at any time

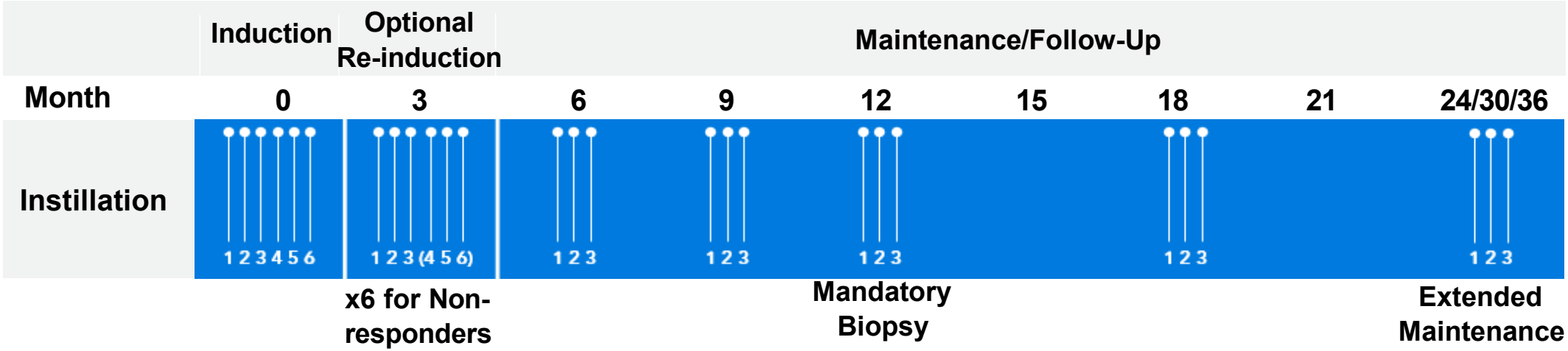
Secondary Endpoints
Duration of Response
CFS, RFS, PFS

Cohort P (N=56):

- Age ≥ 18 yo
- Pathologically confirmed HR BCG-UR NMIBC HG Ta/T1 (Without CIS)
- Completely resected prior to treatment

Primary Endpoint
HG-EFS

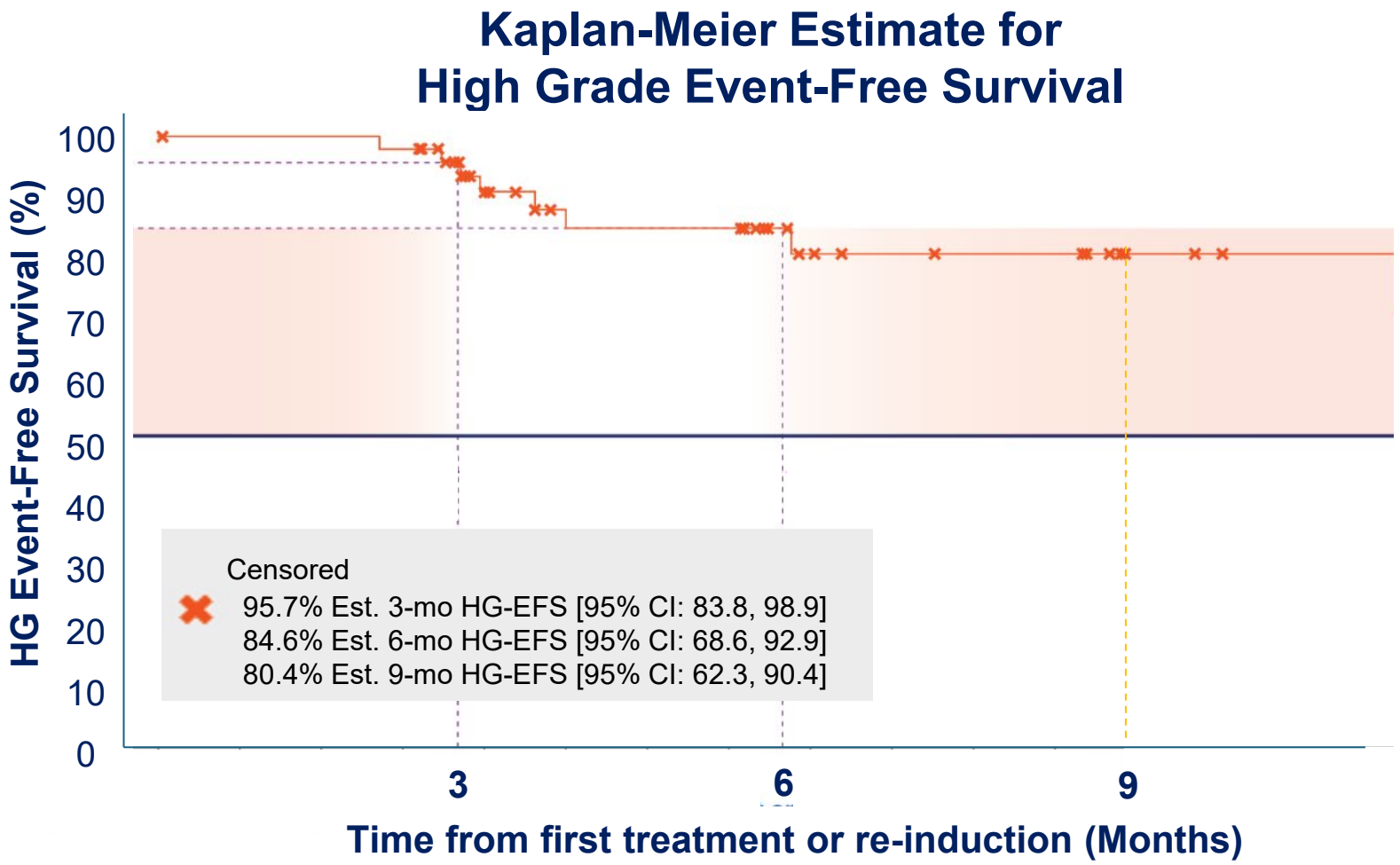
Secondary Endpoints
RFS, PFS, CFS, CSS



CFS= Cystectomy-free survival; CIS= Carcinoma in situ; CSS= Cancer-specific survival; BCG-UR= BCG-Unresponsive; HR= High-Risk; HG-EFS= High-Grade Event-Free Survival; NMIBC= Non-Muscle Invasive Bladder Cancer; PFS= Progression-Free Survival; RFS= Recurrence-Free Survival; RC= Radical Cystectomy

Topline Results: BOND-003 Cohort P

- Demographics: male (78.6%), White (87.5%), >65 yo (75.0%)
- Median follow-up: 6.0 months
- 8 patients were re-induced at 3 months
- Consistent and high HG-EFS
  - HG-Ta:
    - 92.8% (3 mo)
    - 75.9% (6 mo)
    - 75.9% (9 mo)
  - HG-T1:
    - 100% (3 mo)
    - 100% (6 mo)
    - 87.5% (9 mo)
- No patients underwent RC
- No progression to MIBC*



HR= High-Risk; HG-RFS= High-Grade Recurrence-Free Survival; NMIBC= Non-Muscle Invasive Bladder Cancer; RC= Radical Cystectomy
01SEP2025 data cut off. Censored patients include 5 patients pending efficacy assessments.
HG-EFS time from first study treatment (first re-induction dose) to high-grade recurrence, progression, death, or censoring.
* 1 pt progressed to metastatic urothelial carcinoma despite clinical complete response in the bladder.

Consistent, Favorable and Well-Tolerated Safety Profile

Preferred Term (MedDRA v.26.1)	Cretostimogene (n=56)	
	Any Grade (%)	Grade ≥ 3
Patients with ≥ 1 TRAE	40 (71.4%)	0 (0)
Treatment-Related AE reported in > 10% patients		
Bladder Spasm	26 (46.4%)	0 (0)
Dysuria	22 (39.3%)	0 (0)
Pollakiuria	14 (25.0%)	0 (0)
Urgency	11 (19.6%)	0 (0)

- Most AEs were Grade 1-2
- **0% Grade ≥ 3 TRAEs, Serious TRAE, deaths**
- **No dose delays, missed doses due to TRAEs**
- **No treatment related discontinuations**
- 98.2% received all protocol defined treatments

BOND-003 Cohort P: Conclusions

- Topline results with cretostimogene in BOND-003 Cohort P consistently demonstrate
  - Strong HG-EFS at 3, 6, and 9 mo
  - Responses maintained across HGTa and higher-risk, HGT1, populations
  - Well-tolerated safety profile
- Longer-term treatment and follow up ongoing