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BOND-003 Cohort P: A Multi-national, Single-arm Study of Intravesical Cretostimogene Grenadenorepvec for the Treatment of High-Risk, Papillary-Only, BCG-Unresponsive NMIBC

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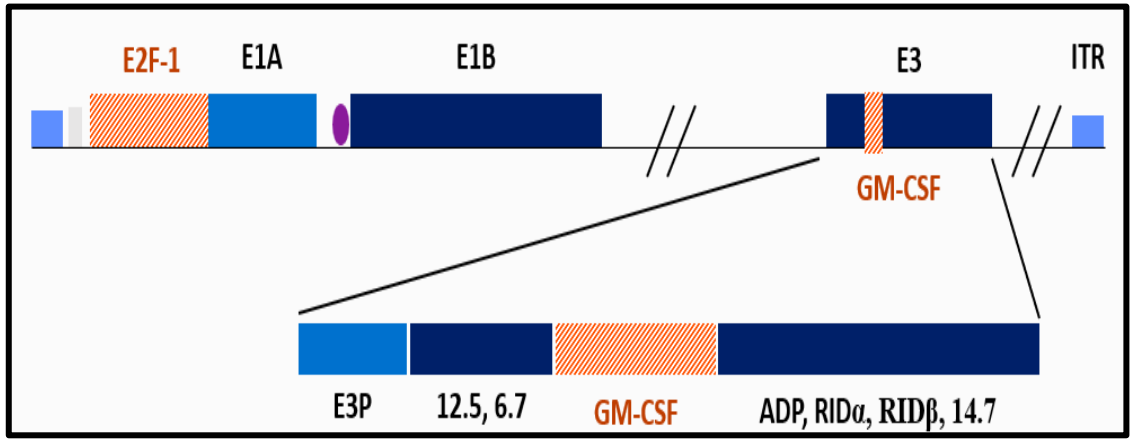
https://cgoncology.com/wp-content/uploads/2024/05/AUA 2024 Tyson_ BOND-003 Cohort P_ Learning Lab_TIP_Presentation Final.pdf

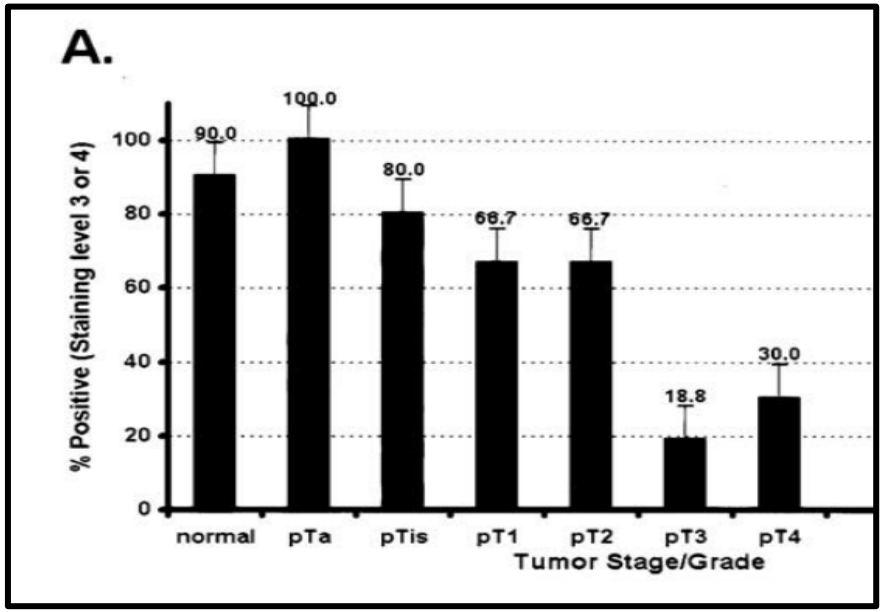
Disclosures

- CG Oncology- No Conflicts of Interest

What is Cretostimogene Grenadenorepvec?

- Conditionally replicating adenovirus
  - Highly immunogenic
- Oncolytic immunotherapy
  - Encodes GM-CSF
  - Insertion of human E2F-1 promoter
- Binds to Coxsackie Adenovirus Receptor (CAR)
  - Robust expression in all stages of bladder cancer
- Viral replication results in tumor lysis





CG Oncology proprietary illustration. Sachs, et al. Urology 2002
Burke, et al J Urol 2012

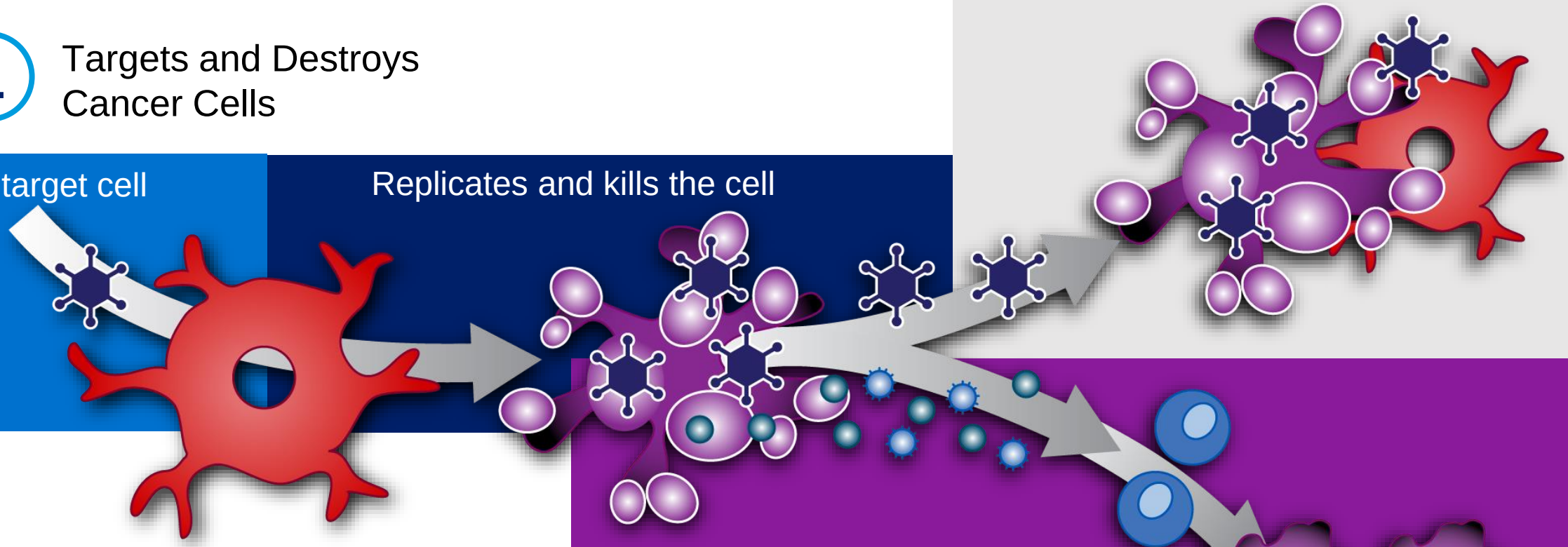
Oncolytic Immunotherapy: Selective Oncolysis and Potent Anti-Tumor Immune Response

1 Targets and Destroys Cancer Cells

Enters target cell

Replicates and kills the cell

Spreads to additional tumor cells inducing a chain reaction of cancer cell death



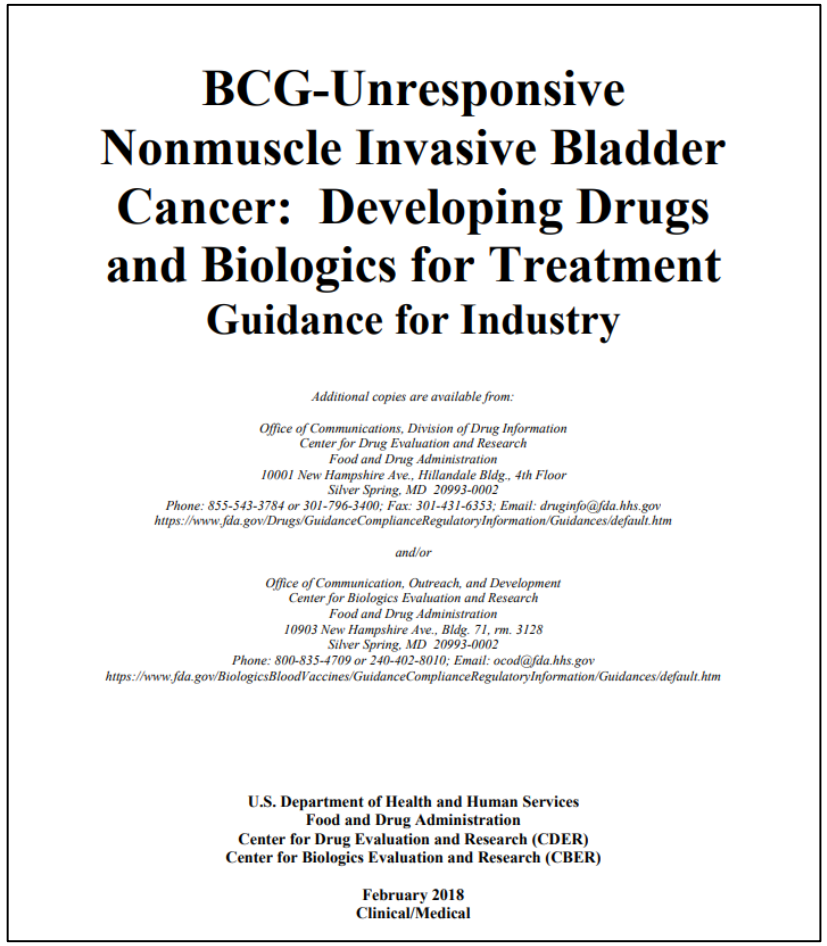
2 Stimulation of Anti-tumor Immune Response

Virus stimulates cytokines and antigens from dying cancer cells which activates T-cells inducing tumor cell death and destruction

BCG-UR NMIBC STUDY DESIGN CONSIDERATIONS

Recommendations from 2018 FDA Guidance

- Single-arm trials appropriate for BCG-UR NMIBC studies
- Primary efficacy endpoints:
  - CR in patients with CIS
  - Time-to-event endpoint for patients with completely resected Ta/T1 disease



BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment

Guidance for Industry

Additional copies are available from:

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Food and Drug Administration
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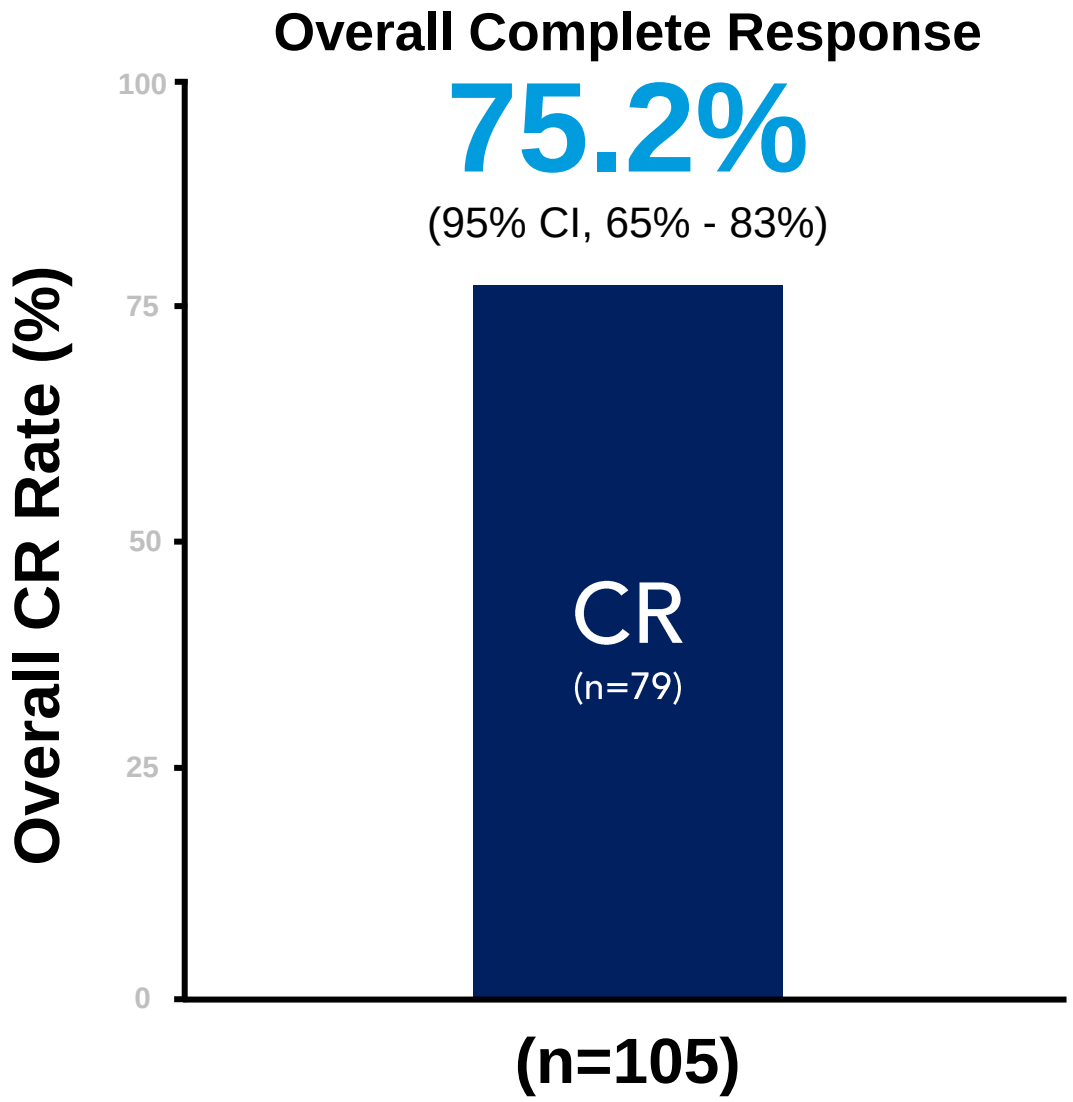
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2018
Clinical/Medical

CIS +/- Ta/T1- Carcinoma *in situ,* with or without Ta/T1; CR- Complete Response; NMIBC- Non-Muscle Invasive Bladder Cancer

FDA Guidance Document: BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment. February 2018 .

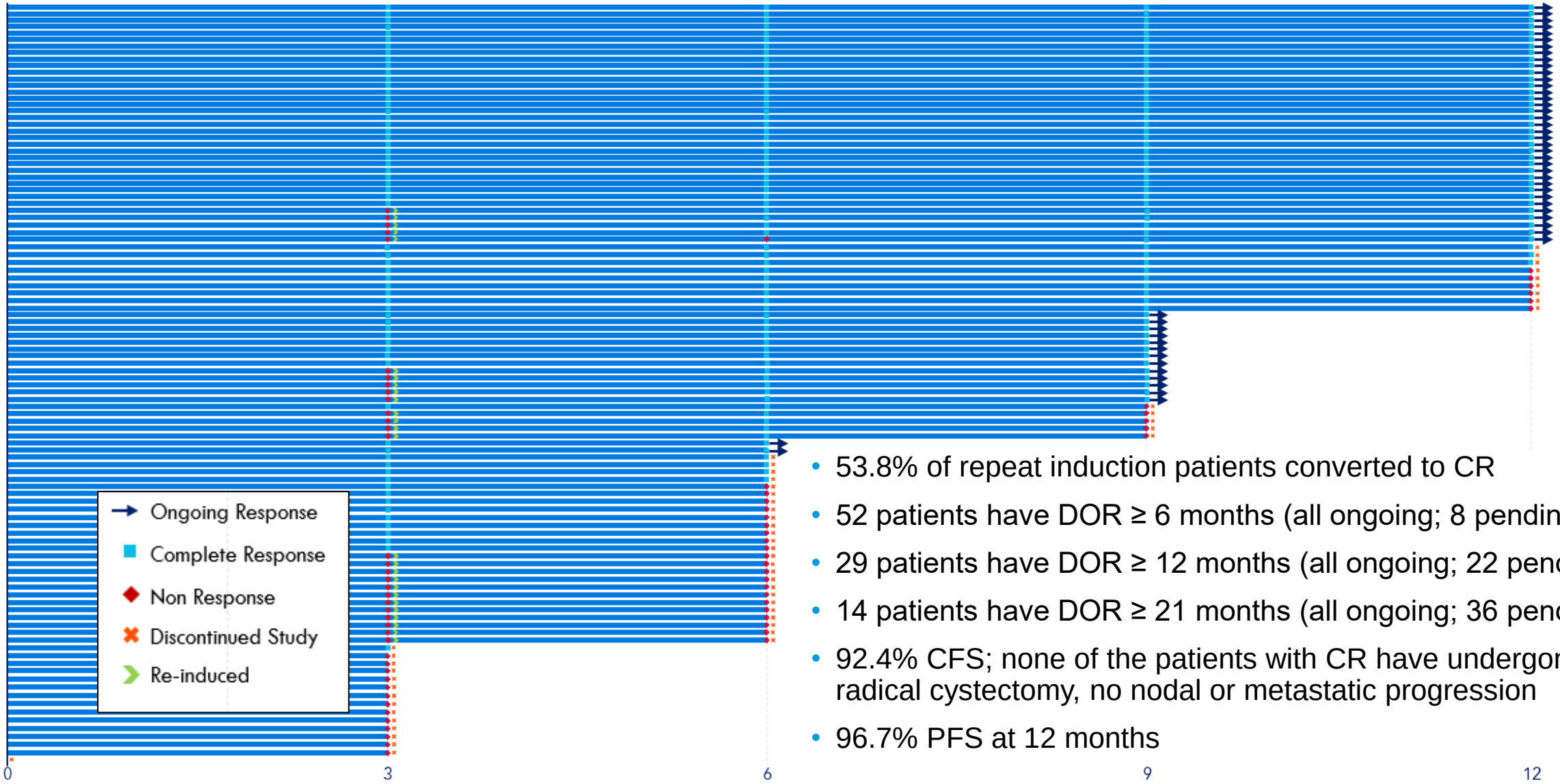
Cretostimogene Monotherapy Results: 75.2% CR at Any Time



Efficacy data cutoff as of 01APR2024

Efficacy analysis centrally confirmed. All pts have active disease at baseline prior to enrollment. Received adequate BCG per FDA 2018 guidance

Cretostimogene Shows Durable Responses Over Time



- 53.8% of repeat induction patients converted to CR
- 52 patients have DOR ≥ 6 months (all ongoing; 8 pending)
- 29 patients have DOR ≥ 12 months (all ongoing; 22 pending)
- 14 patients have DOR ≥ 21 months (all ongoing; 36 pending)
- 92.4% CFS; none of the patients with CR have undergone radical cystectomy, no nodal or metastatic progression
- 96.7% PFS at 12 months

Efficacy data cutoff as of 01APR2024.

Cretostimogene Has Been Generally Well-Tolerated

Preferred Term (MedDRA v.26.1)	Cretostimogene (n=112)	
	Any Grade (%)	Grade ≥ 3
Patients reporting ≥ 1 TRAE	70 (62.5%)	0 (0)
Treatment-Related AE reported in >10% patients		
Bladder Spasm	26 (23.2%)	0 (0)
Pollakiuria	22 (19.6%)	0 (0)
Dysuria	17 (15.2%)	0 (0)
Micturition Urgency	17 (15.2%)	0 (0)
Hematuria	16 (14.2%)	0 (0)

- Most AEs were Grade 1-2
- No grade ≥ 3 treatment-related AEs or deaths reported
- 2 patients (1.8%) had serious treatment-related AEs (Grade 2)*
- 1 patient discontinued treatment due to unrelated AE**
- 94.5% completed all expected treatments

Safety data cutoff as of 31JAN2023
* Treatment-related SAEs were Cystitis noninfective (Grade 2) and clot retention (Grade 2).
** Unrelated AE leading to treatment discontinuation was Hematuria (Grade 2).

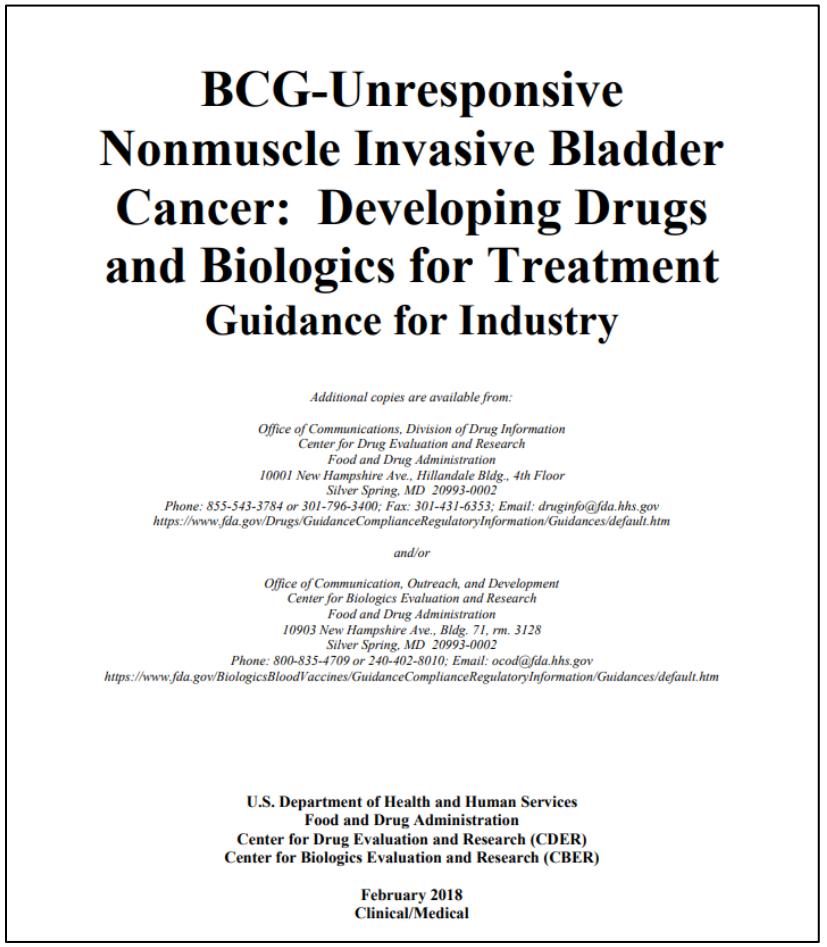
Fast Track & Breakthrough Therapy Designations Granted for Cretostimogene Monotherapy in BCG-UR CIS +/- Papillary Disease!

FDA
Breakthrough Therapy Designation

FDA
Fast Track Designation

Significant Unmet Need for BCG-UR Papillary NMIBC

- Current FDA approved agents for patients with BCG-UR HR NMIBC with CIS +/- Ta/T1[1]
- There is a growing incidence of patients with papillary (Ta/T1) NMIBC[2-3]
- Unmet need for highly effective, well-tolerated, readily available, and durable treatment options for patients with high-risk Ta/T1 papillary disease



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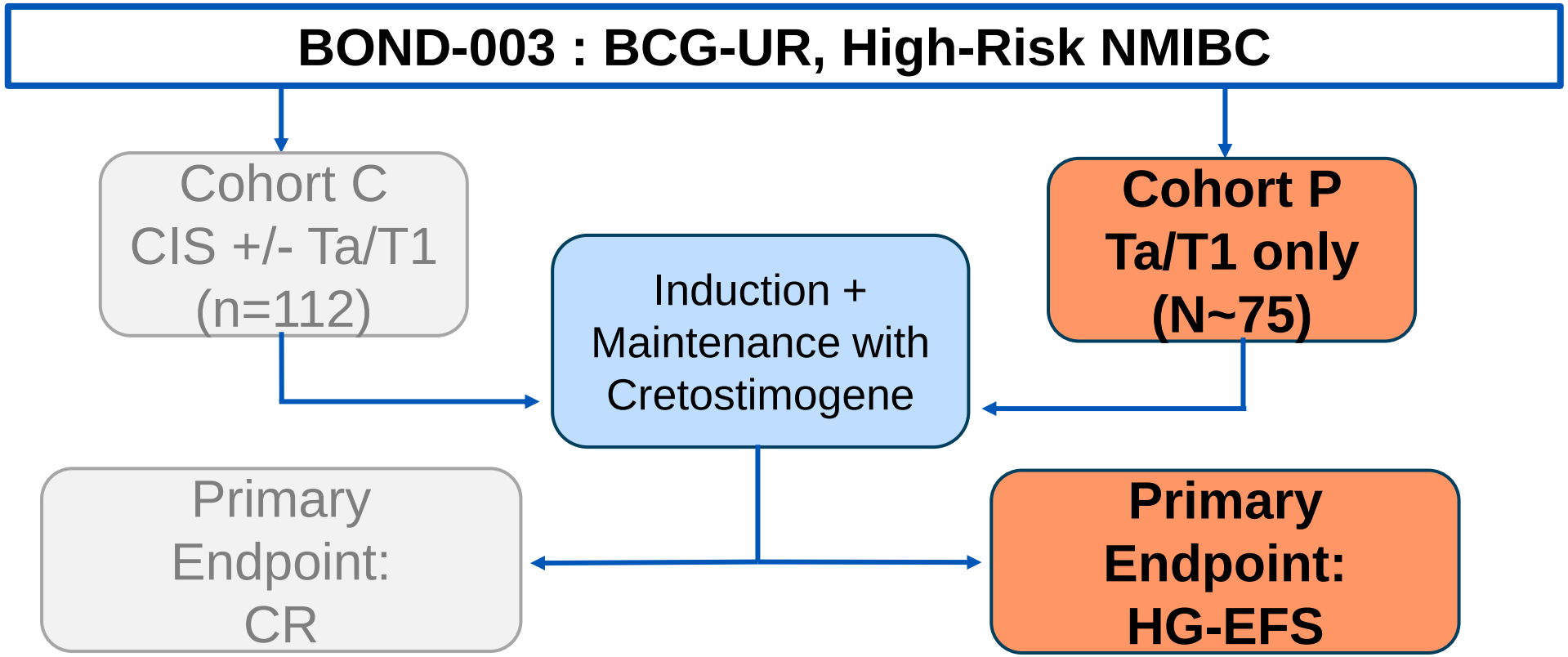
February 2018
Clinical/Medical

BCG- Bacillus Calmette Guerin; CIS +/- Ta/T1- Carcinoma in situ, with or without Ta/T1; NMIBC- Non-Muscle Invasive Bladder Cancer

FDA Guidance Document 2018 .
1 Holzbeierlein J et al., AUA/SUO guideline: 2024 amendment..
2. Nielsen et al 2014. Cancer. 2014 3. Taylor J. Long Term Outcomes of Bladder Sparing Therapy Compared to Upfront Radical Cystectomy in BCG Unresponsive NMIBC in an International Cohort . Presented at: SUO 2023.

BOND-003 Cohort P: BCG-UR, Papillary-Only NMIBC

Study Design



CIS +/- Ta/T1- *Carcinoma in situ,* with or without Ta/T1; CR- Complete Response; EFS- Event Free Survival; NMIBC- Non-Muscle Invasive Bladder Cancer
FDA Guidance Document: BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment. February 2018 .

BOND-003 Cohort P- Papillary Only, BCG-UR, HR-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, PFS, RFS

Cohort P (N~75):

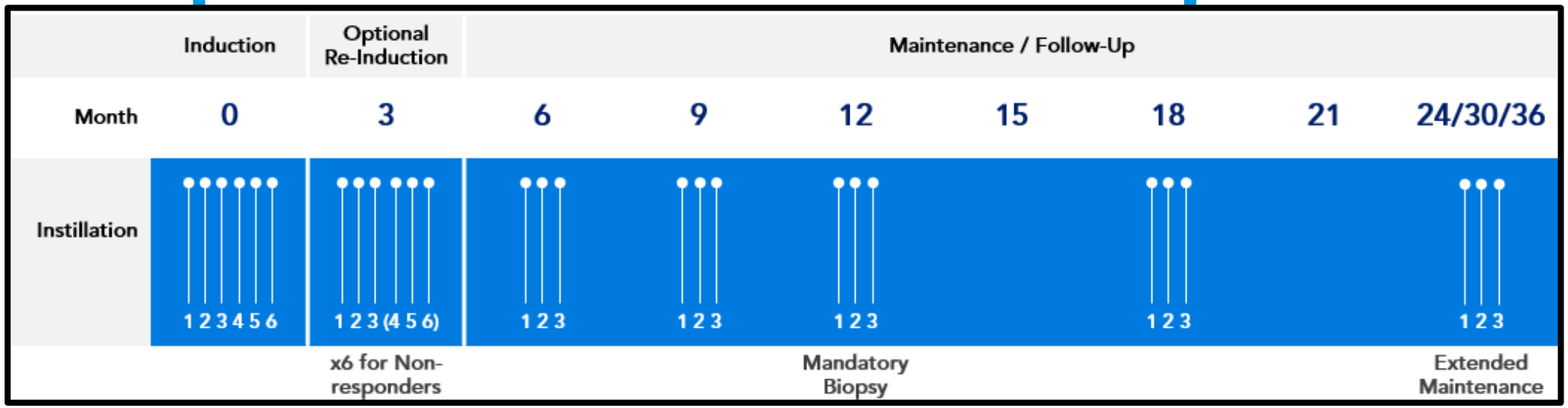
- Age ≥ 18 yo
- Pathologically confirmed BCG-UR HR-NMIBC papillary (Without CIS)
- Completely resected prior to treatment

Primary Endpoint:

- HG-EFS

Secondary Endpoints:

- RFS, PFS, RC-FS, CSS



Experience with Cretostimogene

- Familiar and convenient instillation process/schedule for practices
  - Thaw time up to 10 minutes
- Administered by allied healthcare professionals (MAs, RNs)
- Generally well-tolerated regimen
- 100% of patients with successful instillation on BOND-003
- Streamlined instillation process for future cohorts and studies

BOND-003 COHORT P: TRIAL IN PROGRESS

- First sites opened and patients enrolled March 2024
- First patients dosed
- Anticipated recruitment timeline 12 months
- 35+ sites selected across North America and Japan
- Further site selection is ongoing

- Contact Information:

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Acknowledgements

All Bladder Cancer Patients and Their Families

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BOND-003 COHORT P

BCAN
Bladder Cancer Advocacy Network
Leading the way to awareness and a cure

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THANK YOU & QUESTIONS

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