EAU25
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Trial in Progress: PIVOT-006- A Phase 3, Randomized Study of Adjuvant Intravesical Cretostimogene Grenadenorepvec versus Surveillance for the Treatment of Intermediate-Risk Non-Muscle Invasive Bladder Cancer

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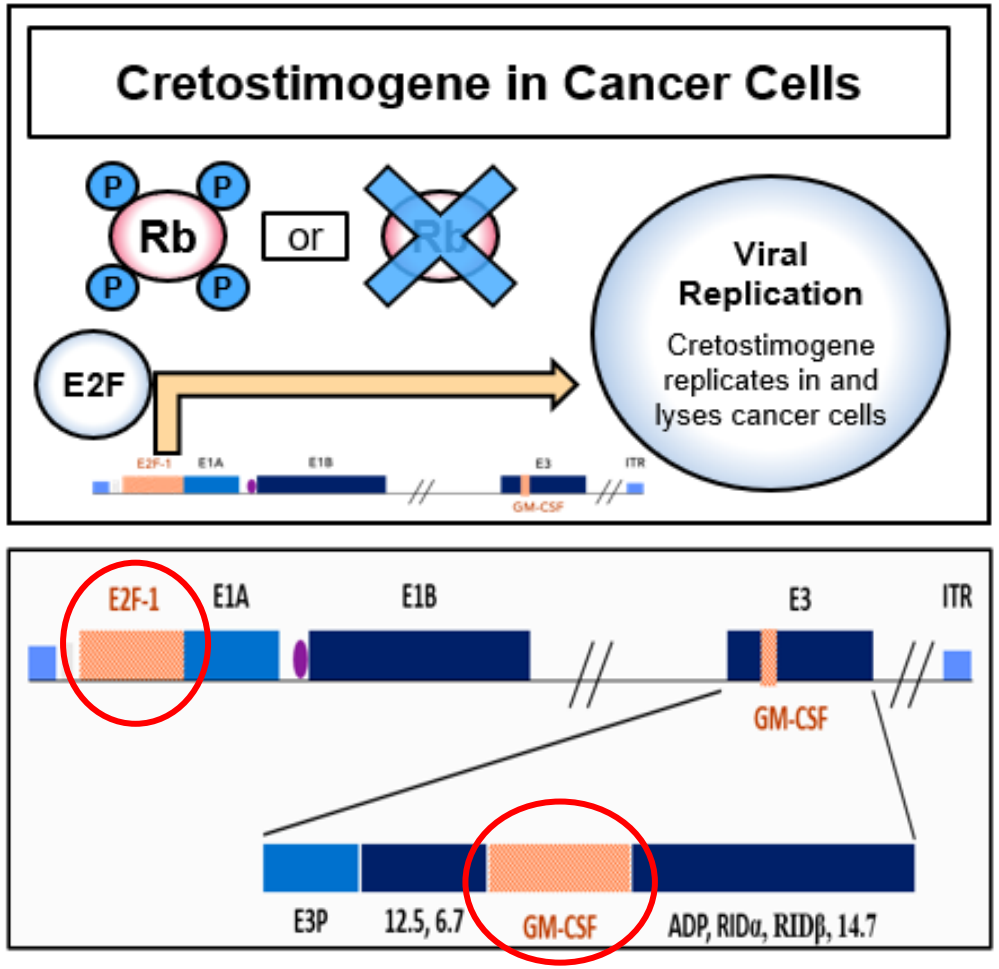
Conflict of Interest Disclosure

- Consultant- CG Oncology

What is Cretostimogene Grenadenorepvec?

- Conditionally replicating, highly immunogenic adenovirus
  - Under regulation of the human E2F-1 promoter
    - Selective for RB-E2F pathway alterations
  - Encodes GM-CSF transgene

- Oncolytic immunotherapy with dual MOA
  - Viral replication results in tumor lysis
  - Stimulation of immune response



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

Intermediate-Risk NMIBC Study Considerations

- Considerable risk of recurrence[1,2]
- No standard of care treatment is approved by the US FDA for IR-NMIBC
- Surveillance as the control arm is appropriate:
  - Best comparator to determine benefit of adjuvant treatment
  - Low risk of progression[1,2]
  - Consistent with guideline-directed care[3,4]
  - Low utilization of intravesical therapy for IR-NMIBC[3,5,6]
  - Prior randomized, controlled trial supports surveillance as comparator[7]

1. Sylvester RJ, et al. *Eur Urol* 2006 2. EAU NMIBC Guideline. Available at: EAU Guidelines on Non-muscle-invasive Bladder Cancer – Uroweb 3.Matulay J, et al. *Urol Oncol* 2020 4. NCCN Clinical Practice Guidelines in Oncology. Bladder Cancer. Version 6. 2024 5. Mori, et al. *Urol Oncol* 2020 6. Lewicki P, et al. *JAMA Open Network* 2022 7. Messing E, et al. *JAMA* 2018

Phase 3 Adjuvant Cretostimogene Versus Surveillance for IR NMIBC

Intermediate-Risk NMIBC

Cretostimogene vs Surveillance
Randomized (1:1), Two Arms, Open-Label (n=364)

Primary Endpoint:
Recurrence-Free Survival

Population / Key Entry Criteria

- AUA definition IR-NMIBC
- Complete resection at baseline
- Adequate organ function & ECOG 0-2
- Stratification for IVE chemo after TURBT, HG vs LG

Study Design / Regimen

- Arm A = IVE Cretostimogene following TURBT
  - Induction= Weekly x 6
  - 1-yr Maintenance= Weekly x 3 at Mos 3, 6 and x 1 at Mos 9, 12
- Arm B = Surveillance after TURBT
  - Patients with disease recurrence eligible to receive cretostimogene

Additional Endpoints

- RFS at 12-month and 24-month
- PFS
- Safety
- Exploratory endpoints: Biomarkers, PROs, HRQoL, health system utilization

NCT06111235

SUO-CTC Trial in Progress: PIVOT-006

- Over 90 North American sites participating
- First enrollments January 2024
- Expected enrollment period – 30 Months
- Rapid enrollment; one-third recruited
- At least 1 year of follow-up
- NCT06111235

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Thank you for your attention!

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