**Development and Validation of Circulating Tumor Cell Enumeration (Epic Sciences) as a Prognostic Biomarker in Men with Metastatic Castration Resistant Prostate Cancer**


Memorial Sloan Kettering Cancer Center.

The primary objective of this pre-specified retrospective analysis is to assess CTC numbers in a group of patients treated with AR signaling inhibitors (ARsi) and compare to counts measured on the FDA approved predicated CellSearch™ Circulating Tumor Cell kit.

**CTC Enumeration in This Study**

- **CellSearch™ Circulating Tumor Cell kit**
- **Affinity Capture by EpCAM**
- **Non-enrichment, all nucleated cells passed onto slides and IF Images: CTCs detected in all iso**
- **Other**
  - affinity capture, microfluidics, size based

**CTC Counts Are a Pre-Treatment Prognostic Biomarker in the Discovery and Validation Cohorts**

- **Epic Sciences Discovery Cohort**
- **CellSearch OS**
  - 1.7 (1.0, 2.9)
- **CellSearch PFS**
  - 1.5 (0.9, 2.3)
- **Multivariable Risk Adjusted Hazard Ratios in the Validation Cohort**
  - **adjusted for therapy line, sites of spread, LDH, PSA, Albumin, Hemoglobin, Alkaline Phosphatase, PSA**
  - **Endpoint**
    - **Overall Survival**
      - **Univariate HR (95% CI); P-value**
        - **CTC/mL ≥ 3**
          - P = 0.03
        - **Fold Change CTC**
          - P = 0.002
    - **Progression-Free Survival**
      - **Univariate HR (95% CI); P-value**
        - **CTC/mL ≥ 3**
          - P = 0.01
        - **Fold Change CTC**
          - P = 0.002

**CONCLUSIONS**

- The findings validate CTC number determined on the Epic Sciences platform as a prognostic biomarker prior to treatment with Androgen Receptor signaling inhibitors in two independent cohorts.
- CTC counts showed strong method agreement and correlation with counts determined using the FDA cleared CellSearch Circulating Tumor Cell kit which is approved as use as an aid to monitoring.
- In univariate and multivariable analyses, the associations of OS and PFS of CTC counts on both platforms were comparable in the Validation cohort.

**FUNDING AND DISCLOSURE STATEMENTS**

- **Research & Development, Janssen, Medivation, Pfizer, Genzyme, Agensys. ESA is a paid consultant/advisor to Janssen, Medivation, Agensys, Genentech, CreaTV and consults for Angle LLT, Axiom LLT, Janssen, OncLive Insights, Menarini Silicon Biosystems, Physicians Education Resource, Pfizer, Sanofi Aventis, and Sanofi**
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