A 17-Gene Assay Drives High Active Surveillance Management in Clinically Low-Risk Prostate Cancer: 1 Year Results from a 1,200 Patient Prospective Observational Trial

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BACKGROUND

• The 17-gene Oncotype DX Genomic Prostate Score® (GPS™) assay is a biopsy-based gene-expression assay validated in clinically low- to intermediate-risk prostate cancer for:
  - Adverse pathology (AP; high grade and/or ≥3+), an early and actionable endpoint (1,2).
  - Distinct metastases and prostate cancer-specific death (3).

• Independent studies of GPS-tested men (N=900) consistently show higher active surveillance use after GPS testing:
  - Up to 30% increase in low-risk men and 15% increase in intermediate-risk men.

RESULTS

Baseline (no GPS)

288 Definitive treatment

Men with clinically low- to intermediate-risk prostate cancer were prospectively enrolled in a 65 (60-69)

Prospective cohort (N=777)∗

489 Active surveillance

446 Evaluated

12-month post-biopsy visit

- Before the GPS test was available at 9 of the sites from the prospective cohort.

- 1,200 patient prospective observational trial of the 17-gene tissue-based RT-PCR GPS assay at 26 sites in the US.

METHODS

- Patient Population
  - Study Design
    - Baseline cohort
    - Active Surveillance cohort
    - Post-GPS cohort

- Study Design
  - Prostate cancer was biopsy validated in clinically low- to intermediate-risk prostate cancer for:
    - AP (high grade and/or 3+)
    - Distinct metastases and prostate cancer-specific death.

- Methods
  - Methodology was similar in all three study groups.
  - Demographics and clinical characteristics were similar between the three study groups.

- Demographics and Clinical Characteristics
  - Age, ethnicity, and race were similar between AS and treated patients.
  - The baseline cohort had similar demographics:
    - 57% < 65 years, 2% Hispanic/Latina, 15% African American, and 15% white.
  - Among NCCN low-risk men, half of patients who were initially recommended definitive treatment changed initial disease management for one in four men.
  - Incorporation of GPS testing provides individualized risk assessment and changes initial disease management for one in four men.
  - Compared to a baseline (no GPS) group, men GPS-tested men went on AS and persistence at 1 year was high.

REFERENCES