



New Study Shows Veracyte's Decipher Prostate Test is Prognostic for Prostate Cancer Progression Among Patients Undergoing Active Surveillance

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 22, 2024-- [Veracyte, Inc.](#) (Nasdaq: VCYT), a leading cancer diagnostics company, today announced that a new study published in [JCO Precision Oncology](#) shows that, among patients undergoing Active Surveillance (AS) for prostate cancer, the Decipher Prostate Genomic Classifier is prognostic for identifying those whose disease is likely to progress. The findings make the Decipher test the only gene expression test to have treatment-outcome data from a prospective, multi-center, phase 2, randomized trial in the AS population.

Patients whose prostate cancer is found at an early stage and who are clinically low or intermediate risk are commonly offered AS, meaning they are closely monitored rather than undergo intervention such as surgery or radiation. Identifying the optimal candidates for active surveillance, however, is not always easy, as clinical indicators are limited in their ability to identify those who may be at a higher risk of future grade reclassification or cancer progression.

"The findings from the ENACT trial analysis demonstrate that the Decipher Prostate test is a predictor of disease progression on AS," said Elai Davicioni, Ph.D., Veracyte's medical director for Urology. "These data also further reinforce Veracyte's commitment to evidence generation that supports the Decipher Prostate test's 'Level 1B' evidence status – the highest among commercially available gene expression tests – in the most recent NCCN® Guidelines* for prostate cancer."

The new findings are from the biomarker analysis study of the ENACT clinical trial (NCT02799745) that aimed to compare the efficacy and safety of enzalutamide monotherapy plus AS vs AS alone in patients with low-risk or intermediate-risk prostate cancer. The study included 121 AS patients from the randomized trial who were monitored and followed for 3 years. In the AS alone or control arm, among patients with available tumor samples (n=65), the Decipher Prostate test predicted increased rates of disease progression after adjusting for baseline clinical risk factors (MVA HR [95% CI] per 10% increase in score: 1.17 [1.01 to 1.35]; $P = 0.04$).

The findings also demonstrated the use of Decipher GRID (Genomic Resource for Intelligent Discovery) as a research tool to help advance scientific understanding of prostate cancer. Specifically, the researchers evaluated whole-transcriptome data derived from Decipher Prostate testing of each sample in the study to assess the Decipher Prostate test and other, research-based biomarkers that could potentially indicate which tumors would be more likely to respond to treatment with enzalutamide, an androgen receptor (AR) signaling inhibitor. They observed that the subset of patients with higher Decipher scores, as well as luminal and high AR activity subtypes, had greater responses to enzalutamide.

"Our Decipher GRID tool enables researchers to analyze whole-transcriptome data for prostate cancer samples to gain further insights about the disease, which can ultimately further improve patient care," said Dr. Davicioni. "This study is a strong example of the Veracyte Diagnostics Platform in action, whereby we use a comprehensive, whole-transcriptome approach to develop a test, which fuels our ability to demonstrate the test's performance and utility, and also enables new discovery efforts."

About the Decipher Prostate Genomic Classifier

The Decipher Prostate Genomic Classifier is a 22-gene test, developed using RNA whole-transcriptome analysis and machine learning, that helps inform treatment decisions for patients with prostate cancer. The test is performed on biopsy or surgically resected samples and provides an accurate risk of developing metastasis with standard treatment. Armed with this information, the physician can better personalize their patients' care and may recommend less-intensive options for those at lower risk or earlier, more-intensive treatment for those at higher risk of metastasis. The Decipher Prostate test has been validated in more than 75 studies involving more than 100,000 patients.

About the Decipher GRID

The Decipher GRID database includes more than 200,000 whole-transcriptome profiles from patients with urologic cancers and is used by Veracyte and its partners to contribute to continued research and help advance understanding of prostate and other urologic cancers. GRID-derived information is available on a Research Use Only basis.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company whose vision is to transform cancer care for patients all over the world. We empower clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Our Veracyte Diagnostics Platform delivers high-performing cancer tests that are fueled by broad genomic and clinical data, deep bioinformatic and AI capabilities, and a powerful evidence-generation engine, which ultimately drives durable reimbursement and guideline inclusion for our tests, along with new insights to support continued innovation and pipeline development. For more information, please visit www.veracyte.com and follow the company on X (formerly Twitter) at @veracyte.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to our statements related to the potential NCCN Guidelines' impact on physicians' better use of the Decipher prostate test and to our expectations that the Decipher Prostate test helps physicians better personalize their patients' care in recommending less intensive versus more intensive treatment options. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "enable," "positioned," "offers," "designed" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to the potential impact Decipher GRID can have on scientific advancements in prostate cancer and, in turn, patients. Additional factors that may impact these forward-looking statements can be found under the caption "Risk Factors" in our Annual Report on Form 10-K filed on March 1, 2024. Copies of these documents, when available, may be found in the Investors section of our website at <https://investor.veracyte.com>. These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim any obligation to update these forward-looking statements or reasons why

actual results might differ, whether as a result of new information, future events or otherwise. These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise.

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