New Data Published in JAMA Oncology Demonstrate Prognostic Utility of Veracyte's Decipher Prostate Genomic Classifier in Locally Advanced Prostate Cancer

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First study demonstrating Decipher Prostate test can inform treatment decisions in nmCRPC

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 14, 2021--

Veracyte, Inc. (Nasdaq: VCYT) today announced new data demonstrating the prognostic utility of the company's Decipher ® Prostate genomic classifier among men with non-metastatic castration-resistant prostate cancer (nmCRPC) have been published online in *JAMA Oncology*. The findings, from a retrospective analysis of patients in the Phase 3 SPARTAN study, suggest that the Decipher test can help identify those patients most likely to benefit from treatment with apalutamide, a second-generation androgen receptor signaling inhibitor (ARSi), in addition to androgen-deprivation therapy (ADT).

"These results suggest that the Decipher Prostate test may be a helpful tool to identify those patients who would benefit from early treatment intensification with androgen receptor inhibitors," said Elai Davicioni, Ph.D., Veracyte's senior vice president, Scientific and Clinical Operations, Urologic Cancers. "As the first clinical evaluation and demonstration of the Decipher test's utility in the nmCRPC setting, this study adds meaningfully to prior evidence demonstrating the test's ability to help inform treatment decisions and improve patient outcomes in multiple prostate cancer settings."

SPARTAN is a multicenter, international, randomized, double-blind, placebo-controlled, Phase 3 trial that investigated the efficacy of adding apalutamide to androgen-deprivation therapy (ADT) in comparison with ADT plus placebo among men with nmCRPC. Results from the trial suggest that the addition of apalutamide to ADT significantly improved metastasis free survival (MFS) and other secondary endpoints in these men.

To understand the molecular characteristics driving the SPARTAN study clinical outcomes, researchers used the Decipher genomic classifier to perform gene expression profiling on archived primary tumor samples from a subset of 233 patients enrolled in the trial. The test stratified patient tumors into Decipher high- and low-to-average-risk groups for metastasis and into basal and luminal subtypes.

The newly published results suggest that Decipher test scores and basal-luminal subtype may be biomarkers of response to apalutamide plus ADT in the nmCRPC setting, and that patients whose tumors were classified as Decipher high-risk or luminal subtype derive the greatest benefit from apalutamide therapy.

Specifically, while study results indicate an MFS improvement among all nmCRPC patients who received apalutamide plus ADT, the 116 patients in the subset who had Decipher high-risk scores exhibited the greatest improvement in MFS (HR 0.21; 95% CI, o.11-0.40; P<0.001) and progression-free survival 2 (PFS2; HR, 0.39; 95% CI, 0.23-0.67; P = 0.001) vs. placebo plus ADT. Notably, the addition of apalutamide to ADT improved the MFS percentage among the Decipher high-risk patients to a level similar to the percentage among patients classified as Decipher low-to-average-risk.

Also, among the apalutamide plus ADT group, those patients whose tumors had the luminal subtype (n=81) experienced a significantly longer MFS compared to those with the basal subtype (n=152; median MFS not reached; HR, 0.40; 95% CI, 0.38-1.60; P=0.50).

Researchers noted that Decipher testing was conducted on samples taken from ADT-naïve patients an average of 6.7 years prior to their enrollment in the SPARTAN study. This suggests that the molecular signatures in initial diagnostic samples taken from primary tumors can be informative for making treatment decisions years later when the cancer has locally advanced.

"These findings are an important addition to our growing understanding about how best to manage patients across the long trajectory of prostate cancer," said Felix Y. Feng, MD, professor of Radiation Oncology, Urology, and Medicine, and vice chair for Translational Research, Department of Radiation Oncology at the University of California, San Francisco, who is a SPARTAN study investigator and the paper's primary author. "They suggest that genomic testing provides useful information to guide treatment decisions that may improve outcomes among men with locally advanced disease, a population for which we've previously lacked genomic biomarkers."

The Decipher Prostate genomic classifier is currently being investigated in seven National Cancer Institute-sponsored, Phase 3, prospective, randomized controlled clinical trials; 13 Phase 2/3 prospective trials; and more than 20 retrospective studies of Phase 3 randomized controlled trials. Many of these trials require Decipher Prostate testing for study inclusion.

About Decipher Prostate

Decipher Prostate (Decipher Prostate Biopsy and Decipher Prostate RP) is a 22-gene, whole-transcriptome-developed genomic test intended to help inform treatment decisions for men with localized prostate cancer at initial diagnosis and after surgical removal of the prostate. The test reports the Decipher Score, which prognosticates a patient's risk of metastasis within five years and provides risk estimates of prostate cancer-specific outcomes. Decipher Prostate can help guide physicians to better select the appropriate therapy for a specific patient, which in turn can result in improved patient outcomes.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global genomic diagnostics company that improves patient care by providing answers to clinical questions, informing diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The company's growing menu of genomic tests leverage advances in genomic science and technology, enabling patients to avoid risky, costly diagnostic procedures and quicken time to appropriate treatment. The company's tests in lung cancer, prostate cancer, breast cancer, thyroid cancer, bladder cancer and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping and renal cancer tests are in development. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its tests to patients worldwide. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, our statements related to our plans, objectives, expectations (financial and otherwise) regarding the Decipher Prostate Genomic Classifier's ability to provide prognostic information that can help physicians tailor treatment decisions for men with prostate cancer. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" 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: Veracyte's ability to achieve and maintain Medicare coverage for its tests; the benefits of Veracyte's tests and the applicability of clinical results to actual outcomes. 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 with the SEC on February 22, 2021 and our subsequent quarterly reports on Form 10-Q. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, Veracyte specifically disclaims 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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