New Data Validate Clinical Utility of Veracyte's Decipher Prostate Genomic Classifier To Help Guide Therapy In Men with Intermediate-Risk Prostate Cancer

February 14, 2022

Findings shared at 2022 ASCO GU Symposium are from the first late-stage clinical study validating any gene-expression test for this patient group

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 14, 2022-- Veracyte, Inc. (Nasdaq: VCYT) announced that new data validating the clinical utility of the company's Decipher Prostate Genomic Classifier for guiding treatment selection in men with intermediate-risk prostate cancer will be presented Thursday, February 17, at the 2022 American Society of Clinical Oncology Genitourinary (ASCO GU) Symposium (Poster #M1). The data, from the randomized, Phase 3 NRG/RTOG 0126 study, confirm initial findings that the Decipher Prostate Genomic Classifier is a prognostic biomarker that can help physicians and patients make personalized treatment decisions in the intermediate-risk setting.

"These findings represent the first high-level evidence of any genomic classifier in intermediate-risk prostate cancer and demonstrate that the Decipher 22-gene biomarker significantly improves prognostic performance across numerous clinically meaningful endpoints," said Daniel Spratt, M.D., chair of Radiation Oncology at University Hospitals Seidman Cancer Center and professor and chair of the Department of Radiation Oncology at Case Western Reserve University School of Medicine, and lead investigator for the study.

Prostate cancer deemed "intermediate risk" by the National Comprehensive Cancer Network (NCCN) Guidelines ® for Prostate Cancer is the most heterogenous of all risk groups in prostate cancer, and there are a wide variety of treatment options available. The Decipher Prostate Genomic Classifier is a prognostic biomarker that provides additional information about the aggressiveness of individual patients' cancer to help physicians more accurately categorize their risk and select appropriate treatments. The study conducted by Dr. Spratt and colleagues confirms findings from prior Phase 2 studies and validates for the first time the test's performance in men with intermediate-risk disease using multi-center Phase 3 trial data.

To assess the prognostic performance of the Decipher Prostate test in the intermediate-risk, post-biopsy setting, researchers utilized patient biopsy samples from the phase 3, randomized NRG/RTOG 0126 trial. This study enrolled men with intermediate-risk prostate cancer, and then compared clinical outcomes following randomization to two different doses of radiation therapy (70.2 Gy vs 79.2 Gy) without hormone therapy. Researchers generated classifier data for each of 215 biopsy samples, then linked the data with clinical outcomes assessing multiple oncologic and survival endpoints. Patients were followed for a median of 12.8 years.

The findings, which will be presented for the first time at ASCO GU this week, show that the Decipher Prostate test was independently prognostic for all clinical endpoints, including disease progression (sub-distribution hazard ratio [sHR] 1.12, 95%CI 1.0-1.26, p=0.04), biochemical failure (sHR 1.22, 95%CI 1.1-1.37, p<0.001), distant metastasis (sHR 1.28, 95%CI 1.06-1.55, p=0.01), prostate cancer-specific mortality (sHR 1.45, 95%CI 1.2-1.76, p<0.001), distant metastasis-free survival (sHR 1.12, 95%CI 1.03-1.23, p=0.009), and overall survival (sHR 1.11, 95%CI 1.01-1.21, p=0.03).

Men in the study with disease classified as Decipher "high-risk" had worse 10-year oncologic and survival outcomes compared to those whose disease was classified as Decipher "low-risk." Based on this finding, men with NCCN intermediate-risk prostate cancer whose disease is classified as Decipher "high-risk" may have improved outcomes with treatment intensification (i.e., the addition of hormone therapy), while men with disease classified as Decipher "low-risk" may have favorable outcomes with radiotherapy alone.

The study also evaluated – within Decipher risk groups - the clinical impact of receiving lower- vs. higher-dose radiation. Among patients with lower Decipher risk scores, the difference in 10-year distant metastasis rates between those who received 70.2Gy vs. 79.2Gy was low (5%). However, among those with higher Decipher scores, the difference was 26%, suggesting that men whose disease is Decipher "high-risk" receive more benefit from the higher dose of radiation than their "low-risk" counterparts.

"This is an important study that provides further evidence for Decipher Prostate and demonstrates how this test could help physicians better personalize treatment for their patients with intermediate-risk prostate cancer," said Elai Davicioni, Ph.D., Veracyte's senior vice president of Scientific and Clinical Operations, Urologic Cancers.

Informing Treatment in Asian Men with Prostate Cancer

In a second ASCO GU Symposium presentation scheduled for this Thursday (Poster #M4), researchers will share data from a study that evaluated the clinical utility of the Decipher Prostate Genomic Classifier in Asian men with prostate cancer, as well as the genomic differences between prostate cancer in Asian vs. Caucasian men enrolled in a 80,829-patient cohort. In a retrospective analysis of Asian men treated at the National Cancer Centre of Singapore, researchers found that Decipher "high-risk" scores were significantly associated with worse metastasis-free survival (hazard ratio 5.22, 95% CI:1.08–25.3, p=0.04). Additionally, the study found substantial differences in tumor biology between Asian and North American men with prostate cancer.

"This is the first report on the performance of the Decipher Prostate test for predicting aggressive disease in Asian men. We commend the researchers in Singapore for their efforts to investigate this question and to add to the existing body of evidence supporting Decipher's validity in men of African and European descent," said Dr. Davicioni. "The findings from this study could help inform personalized treatment recommendations for Asian men with prostate cancer, and, more broadly, deepen our understanding of tumor biology that could benefit all men with the disease."

About Veracyte

Veracyte (Nasdaq: VCYT) is a global 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 diagnostic tests leverages 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, colon cancer, and idiopathic pulmonary fibrosis are available to patients and its renal cancer and lymphoma subtyping tests are in development, the latter as a companion diagnostic. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its genomic 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) or intentions with respect to the Decipher Prostate genomic classifier. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," “suggest,” "may," "will" “prospective” and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. Examples of forward-looking statements include, among others, statements regarding Veracyte’s belief that its Decipher Prostate genomic classifier can help guide treatment among men with intermediate-risk prostate cancer. 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.

Veracyte, the Veracyte logo, HalioDx, Decipher, Decipher GRID, Afirma, Percepta, Envisia, Prosigna, Lymphmark, “Know by Design” and “More about You” are registered trademarks of Veracyte, Inc. and its affiliates in the U.S. and selected countries. nCounter is the registered trademark of NanoString Technologies, Inc. in the U.S. and selected countries and used by Veracyte under license.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220214005875/en/

Investor and Media Contact:
Tracy Morris
Vice President of Corporate Communications
& Investor Relations
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.