



Data Presented at ASTRO 2021 Validate Prognostic Value of Decipher Prostate Genomic Test in Newly Diagnosed, Clinically High-Risk Prostate Cancer

October 25, 2021

- First validation of a gene expression classifier in pre-treatment biopsy samples from prospective randomized trials -

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 25, 2021-- [Veracyte, Inc.](#) (Nasdaq: VCYT) announced today that new data being presented at the American Society for Radiation Oncology (ASTRO) 2021 Annual Meeting suggest the company's Decipher Prostate genomic classifier identifies patients with clinically high-risk prostate cancer who may require treatment intensification beyond standard-of-care therapy.

The findings, from a pre-specified analysis of biopsy samples taken from prostate cancer patients with clinically high-risk disease who were enrolled in multiple phase 3, prospective, randomized studies, show that Decipher Prostate test scores are independently associated with distant metastases (DM), prostate cancer-specific mortality (PCSM) and overall survival (OS) in this patient population. After a median follow up of 11 years, men with disease classified as Decipher high-risk experienced substantially less favorable outcomes compared to men with disease classified as Decipher low-risk.

"Clinically high-risk prostate cancer is a heterogeneous disease, and having reliable information about individual patients' prognoses based on their unique tumor biology can help improve shared decision-making," said Paul L. Nguyen, M.D., of the Dana-Farber Brigham Cancer Center, who presented the data during an ASTRO media briefing today. "The findings we're sharing at ASTRO are particularly exciting because they are the first to validate use of a gene expression classifier in pre-treatment prostate cancer biopsy samples collected during prospective, randomized clinical trials."

For the analysis, Dr. Nguyen and colleagues obtained Decipher Prostate scores for 265 biopsy samples from the NRG/RTOG 9202, 9413 and 9902 phase 3 randomized trials. After multi-variable analyses adjusting for age, prostate-specific antigen (PSA) levels, Gleason score, cT-stage, trial and randomized treatment arm, researchers found that Decipher Prostate scores were independently associated with distant metastases (HR 1.24), prostate cancer-specific mortality (1.27) and overall survival (1.12). The cumulative incidence of DM at 10 years was 26%, 15% and 6% for men who were Decipher high-risk, intermediate-risk and low-risk, respectively. Among the subset of patients with a Decipher Prostate score >0.85 (within the "high-risk" range of 0.6-1.0), DM was 29% at 5 years and 41% at 10 years.

"This analysis provides the first clinical evidence that the Decipher Prostate classifier can help physicians and patients make critical, personalized treatment decisions in the post-biopsy, clinically high-risk prostate cancer setting," said Elai Davicioni, Ph.D., Veracyte's senior vice president of scientific and clinical operations, Urologic Cancers. "It adds another important piece to the extensive and growing body of clinical data supporting use of the classifier to help inform treatment decisions across the patient's prostate cancer journey."

Treatment intensification for men with clinically high-risk prostate cancer and Decipher scores above 0.85 is being studied in the currently enrolling, prospective, phase 3 randomized trial NRG-GU009 (PREDICT-RT), which also studies treatment de-intensification by halving the duration of hormonal therapy in men with Decipher scores 0.85 or less. Along with PREDICT-RT, 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 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 assist healthcare providers in selecting patient treatment options. 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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