May 25, 2021

Veracyte Announces New Data at ASCO 2021 Reinforcing Prognostic Utility of Decipher Prostate Genomic Classifier

- VANDAAM study findings confirm test predicts aggressive prostate cancer in African American men -

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 25, 2021-- Veracyte, Inc. (Nasdaq: VCYT) today announced new data from two studies that further demonstrate the Decipher® Prostate Genomic Classifier (GC) provides prognostic information that can help physicians tailor treatment decisions for men with prostate cancer. The findings will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held virtually June 4-8, 2021.

In an oral presentation on June 8, researchers will share initial results from the ongoing, prospective VANDAAM (Validation Study on the Impact of Decipher Testing on Treatment Recommendations in African American and Non-African American Men with Prostate Cancer) Study (Abstract 5005). The findings confirm that the Decipher GC predicts aggressive prostate cancer in African American men (AAM) with the same accuracy as in non-African American men (NAAM), and performs better than standard clinical-risk factors or nomograms in this population.

“Our findings show that integrating the Decipher Genomic Classifier into the standard clinical workup for African American men with prostate cancer could improve accuracy in disease-risk classification and optimize treatment recommendations,” said Kosj Yamoah, M.D., Ph.D., of Moffitt Cancer Center, who will present the study findings. “These findings are important because they are the first to confirm the Decipher test’s performance among African American men with prostate cancer – a population that previous data have shown to be more susceptible to aggressive forms of the disease.”

Using the Decipher GC, researchers assessed risk of disease metastasis among a robustly matched cohort of 207 (102 AAM, 107 NAAM) prostate cancer patients who were newly diagnosed with low to intermediate clinical-risk disease as defined by National Comprehensive Cancer Network (NCCN) guidelines for the management of prostate cancer. Analysis revealed significant genomic differences between AAM and NAAM across NCCN risk groups. Among men with NCCN low to favorable-intermediate clinical-risk disease, 49% of AAM harbored high genomic-risk tumors, as compared to only 10% of NAAM (p=0.02). Additionally, AAM were 3.9 times more likely to be reclassified as high risk for distant metastasis as compared to NAAM (RR = 3.99, 95% CI, 1.15-13.86, p=0.02) using a clinico-genomic risk classifier that comprised both Decipher score and clinical variables.

Additional Decipher GC findings to be presented at ASCO include new data from a retrospective analysis of samples in the Phase 3 randomized Swiss Group for Clinical Cancer Research (SAKK) 09/10 trial (Abstract 5010), which evaluated conventional-dose (64Gy) salvage radiotherapy (SRT) vs. a dose-escalated SRT regimen (70Gy) in men with biochemical recurrence after radical prostatectomy (RT). In both arms of the study, patients received SRT without concurrent androgen deprivation therapy (ADT). Researchers tested samples from 226 SAKK 09/10 study participants using the Decipher GC to evaluate its ability to predict freedom from prostate specific antigen (PSA) recurrence, as well as clinical progression-free survival (CPFS) and progression to use of ADT.

“For men experiencing a biochemical recurrence following radical prostatectomy, it has been unclear which will have favorable outcomes from SRT without concurrent ADT, and which men should receive concurrent ADT in order to reduce their likelihood of progression,” said Alan Dal Pra, M.D., of Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine, who will present the study findings. “This first-of-its-kind analysis validates Decipher GC in a contemporary cohort of patients providing valuable, objective information to help physicians make confident treatment decisions that could optimize patient outcomes.”

Study results show that patients with a Decipher high-risk score receiving SRT without concurrent hormone therapy were more than twice as likely as those with a Decipher low- or intermediate-risk score to experience biochemical progression (HR 2.10 ([95% CI 1.34-3.30], p=0.001) and clinical progression (HR 2.26 [95% CI 1.36-3.75], p=0.002), and almost three times as likely to progress to usage of ADT (HR 2.75 ([95% CI 1.48-5.11], p=0.002). Decipher high-risk patients who received conventional SRT had a five-year freedom from biochemical progression of 51% (95% CI 32-70) vs. 39% for those who received dose-escalated SRT (95% CI 20-59); for Decipher low-risk patients, five-year freedom from biochemical progression was 75% (95% CI 65-84) among those who received conventional SRT vs. 69% (95% CI 59-78) among those who received dose-escalated SRT.

“By independently assessing the underlying biology of prostate tumors, the Decipher Prostate Genomic Classifier accurately predicts individual patients’ disease prognosis to enable more informed therapeutic decisions,” said Bonnie Anderson, Veracyte’s chairman and chief executive officer. “The VANDAAM and SAKK 09/10 studies provide additional, highly credible evidence of the test’s clinical value, and should solidify it as standard-of-care for men with prostate cancer.”

About Decipher Prostate

Decipher Prostate (Decipher Prostate Biopsy and Decipher Prostate RP) is a 22-gene, microarray-based 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. The risks and uncertainties may be amplified by the COVID-19 pandemic, which has caused significant economic uncertainty. The extent to which the COVID-19 pandemic impacts Veracyte's businesses, operations, and financial results, including the duration and magnitude of such effects, will depend on numerous factors, which are unpredictable, including, but not limited to, the duration and spread of the outbreak, its severity, the actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume. 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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