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Data Published in "The Red Journal" Validate Clinical Utility of Veracyte's Decipher Prostate Genomic Classifier To Help Guide Therapy in Men with Intermediate-Risk Prostate Cancer

Findings represent first validation of any gene expression biomarker for intermediate-risk patients using data from a randomized phase 3 clinical trial

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 2, 2023-- Veracyte, Inc. (Nasdaq: VCYT) announced that data published in the *International Journal of Radiation Oncology, Biology, Physics* (aka, "The Red Journal") validate the clinical utility of the company's Decipher Prostate Genomic Classifier for helping to guide treatment selection in men with intermediate-risk prostate cancer. The findings are from NRG Oncology/RTOG 0126, a Phase 3 randomized clinical trial of patients with intermediate-risk prostate cancer treated with definitive radiotherapy without concomitant hormone therapy. This is the first randomized study to validate any gene-expression biomarker in this patient population, adding further evidence to support the Decipher Prostate test's utility.

"Physicians have historically relied on clinical and pathological variables such as the Gleason score to guide the use of radiation treatment and the addition of androgen deprivation therapy to radiotherapy for men with intermediate-risk prostate cancer. However, these tools have only modest ability to accurately discriminate individual patients' prognosis, leading to a long-standing challenge of both under- and over-treatment of these men," said Daniel Spratt, M.D., Vincent K. Smith 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. "The findings from this study suggest that the Decipher Prostate test provides reliable and clinically meaningfully risk-stratification that may enhance personalized decision-making in the intermediate-risk setting."

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 personal risk and select appropriate treatments. The study conducted by Dr. Spratt and colleagues confirms findings from prior studies and validates for the first time the test's performance in men with intermediate-risk disease using a multi-center, Phase 3 randomized trial.

To assess the prognostic performance of the Decipher Prostate test in the intermediate-risk, post-biopsy setting, researchers utilized patient biopsy samples from the NRG/RTOG 0126 National Cancer Institute-sponsored clinical trial. This study enrolled patients 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 any concurrent hormone therapy (aka, androgen deprivation therapy, or ADT). Researchers generated Decipher scores for 215 patients from their 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.

Results show that the Decipher Prostate test was independently prognostic for all clinical endpoints, including disease progression (sub-distribution hazard ratio [sHR] 1.12), biochemical failure (sHR 1.22), distant metastasis (sHR 1.28), and prostate cancer-specific mortality (sHR 1.45). Overall, men in the study with higher Decipher Prostate test scores had worse 10-year outcomes with radiotherapy (RT) alone compared to men with lower Decipher Prostate test scores. The 10-year rate of distant metastasis among men with lower Decipher Prostate test scores was 4%, as compared to 16% among those with higher scores.

The published 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 low-dose radiation therapy (70.2Gy) vs. high-dose radiation therapy (79.2Gy) was lower (-7%). However, among those with higher Decipher scores, the difference was 21%, suggesting that men with higher Decipher scores receive more benefit from the higher dose of radiation than those with lower scores. "While this requires further validation, this signal of a biomarker-radiotherapy dose interaction is very rare in oncology, and deserves further exploration," Spratt said.

"This study suggests that using the Decipher Prostate test to more precisely determine prognosis and risk for men with intermediate-risk prostate cancer – and thereby potentially optimizing individual treatment decision-making – could help resolve a long-standing challenge in prostate cancer care and have a meaningful clinical impact for these patients," said Elai Davicioni, Ph.D., Veracyte's medical director for Urology.

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 high-performing tests enable clinicians to make more confident diagnostic, prognostic, and treatment decisions for some of the most challenging diseases such as thyroid, prostate, breast, bladder and lung cancers, as well as interstitial lung diseases. We help patients avoid unnecessary procedures and speed time to diagnosis and appropriate treatment. In addition to making our tests available in the U.S. through our central laboratories, we also aim to deliver our tests to patients worldwide through a distributed model to laboratories that can perform them locally. 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 our clinical tests in and outside of the United States. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "positioned," "designed" and similar references to future periods. Examples of forward-looking statements include, among others, that: the Decipher Prostate Genomic Classifier can help guide treatment for men with intermediate-risk prostate cancer; the Decipher Prostate test provides reliable and clinically meaningfully

risk-stratification that may enhance personalized decision-making in the intermediate-risk setting; the Decipher Prostate test may more precisely determine prognosis and risk for men with intermediate-risk prostate cancer; the Decipher prostate test may optimize individual treatment decision-making; the Decipher prostate test could help resolve a long-standing challenge in prostate cancer care and have a meaningful clinical impact for these patients; higher Decipher scores may have improved outcomes with treatment intensification (i.e., the addition of hormone therapy), while men with lower Decipher scores may have favorable outcomes with radiotherapy alone. 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 February 22, 2023, and our Quarterly Report on Form 10-Q filed for the three months ended December 31, 2022. 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.

Veracyte delivers the Decipher Prostate Genomic Classifier from its CLIA laboratories. Those tests are not CE-IVD marked and have not been cleared or approved by the FDA; their performance characteristics were determined by Veracyte and they might be considered for Research Use Only in some markets. Please contact Veracyte for confirmation.

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Investors:
Shayla Gorman
Director, Investor Relations
investors@veracyte.com
619-393-1545

Media:
Tracy Morris
Vice President of Global Corporate Communications
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.