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New Data Published in JNCI Demonstrate Veracyte's Decipher Prostate Genomic Classifier May Improve Identification of Aggressive Prostate Cancer in African American Men

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 22, 2022-- Veracyte, Inc. (Nasdaq: VCYT) announced that data published today in the *Journal of the National Cancer Institute* demonstrate that the company's Decipher Prostate Genomic Classifier may help identify African American men with early, localized prostate cancer who are most likely to harbor more aggressive disease. The data, from the prospective, multi-site VANDAAM Phase 2 clinical study, suggest that the genomic test may offer a robust improvement over clinical factors alone in risk-stratifying prostate cancer among African American men, which may help reduce disparities in prostate cancer outcomes.

"While African American men have both higher incidence and mortality associated with prostate cancer, few prospective studies maximize recruitment of these men to provide an unbiased assessment of the genomic processes that underlie these disparities," said Kosj Yamoah, MD, Ph.D., chair, Department of Radiation Oncology, Moffitt Cancer Center, and lead author on the published paper. "We very intentionally recruited a balanced sample of men into this study, but prioritized recruitment of African American men first in order to ensure we had a representative sample of this population, which historically has been underserved in prostate cancer clinical trials. The integration of the Decipher classifier with traditional clinical risk factors was shown to improve identification of the subset of African American men with more aggressive disease. This information could help guide targeted interventions and treatment strategies to improve outcomes in this population."

The Decipher Prostate Genomic Classifier is a 22-gene prognostic biomarker that provides a low, intermediate or high score indicating the aggressiveness of an individual patient's cancer, to help healthcare professionals more accurately categorize risk and select appropriate treatment.

The VANDAAM trial enrolled men with low- or intermediate-risk prostate cancer as classified by the National Comprehensive Cancer Network (NCCN) Guidelines® for Prostate Cancer. For the current analysis, researchers identified a clinically balanced cohort of 226 men (113 African American men and 113 non-African American men) from the study and performed genomic analysis using the Decipher Prostate classifier to generate Decipher risk scores.

Results show that a higher proportion of African American men with NCCN low and favorable intermediate risk prostate cancer (18% and 37.8%, respectively) had higher Decipher scores as compared to non-African American men. Men who self-identified as African American were more than twice as likely as non-African American men to have their cancer re-classified from NCCN low or intermediate risk based on a high Decipher score (known as genomic risk of reclassification or GrR; relative risk = 2.23; 95% CI). In addition, the data show that younger African American men had higher Decipher scores, whereas in non-African American men, higher risk of metastasis scores were observed in older men.

"This study demonstrates that prostate cancer risk classification using clinical factors alone may be suboptimal and may underestimate African American men's risk of harboring aggressive disease," said Elai Davicioni, Ph.D., Veracyte's medical director, Urology. "We commend the study team for undertaking the first prospective trial to utilize genomic classifiers as part of the trial design, as well as for their efforts to help close the clinical disparity gap by improving risk stratification among African American men with prostate cancer."

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company that improves patient care by answering important clinical questions to inform diagnosis and treatment decisions. Our growing menu of advanced diagnostic tests help patients avoid risky, costly procedures and interventions, and reduce time to appropriate treatment. In addition to making our tests available in the United States through our central laboratories, our exclusive license to our best-in-class diagnostics instrument (nCounter Analysis System) positions us to deliver our tests to patients worldwide through 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. An example of a forward-looking statement includes, among others, that the Decipher Prostate Genomic Classifier may offer a robust improvement over clinical factors alone in risk-stratifying and appropriately managing prostate cancer among African American men with early-stage disease and integration of the Decipher classifier with traditional clinical risk factors could help guide targeted interventions and treatment strategies to improve outcomes in this population. 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 28, 2022, and our Quarterly Report on Form 10-Q to be filed for the three months ended June 30, 2022. Copies of these documents, when available, may be found in the Investors section of our website at www.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. This piece is distributed purely for educational purposes and is not intended to promote or encourage any off-label use of Veracyte products.

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