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Data Published in “The Red Journal” Validate Prognostic Value of Veracyte’s Decipher Prostate Genomic Classifier for Men with High-Risk Prostate Cancer

- Decipher Prostate test improves risk-stratification to help reduce under- and over-treatment -

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 15, 2023-- [Veracyte, Inc.](#) (Nasdaq: VCYT) today announced that data published in the [International Journal of Radiation Oncology, Biology, Physics](#) (aka, “The Red Journal”) demonstrate that the company’s Decipher Prostate Genomic Classifier can improve risk stratification among men with clinically high-risk prostate cancer. The data, from a pre-specified analysis of three phase 3 trials, represent the first validation of any gene-expression biomarker on pre-treatment biopsy samples from prospective randomized trials, and suggest the Decipher test provides clinically useful prognostic information to help personalize shared treatment decision-making.

Approximately 30% of men with newly diagnosed localized prostate cancer present with high-risk disease, meaning they have an increased risk of disease recurrence, metastasis and death compared to men with lower-risk disease. However, previous studies have shown that more than 70% of men with high-risk prostate cancer who receive standard-of-care definitive radiotherapy and long-term androgen deprivation therapy (ADT) will never develop metastatic disease.

“High-risk prostate cancer is heterogenous and standard prognostic tools do a poor job of discriminating which men are likely to develop distant metastases and may benefit from more aggressive therapy, and who will do well when treated with standard radiotherapy and ADT,” said Paul L. Nguyen, M.D., vice-chair for Clinical Research in the Department of Radiation Oncology at The Dana Farber/Brigham Cancer Center and professor at Harvard Medical School, and lead author of the published manuscript. “Because of this, clinicians are forced to use a one-size-fits-all approach that inherently leads to under- and over-treatment of many men. The data published today validate the role of the Decipher Prostate test in more accurately prognosticating patient outcomes, even within a high-risk group, to better personalize care. This utility is being further examined prospectively in ‘PREDICT-RT’, two parallel, randomized phase 3 clinical trials conducted by NRG Oncology and sponsored by the National Cancer Institute.”

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.

For the current analysis, Dr. Nguyen and colleagues obtained Decipher test scores on 265 biopsy samples from men with prostate cancer that was designated “high-risk” by National Comprehensive Cancer Network (NCCN) classification and who participated in one of three NRG Oncology randomized Phase 3, definitive radiotherapy trials (RTOG 9202, RTOG 9413 and RTOG 9902). With a median follow-up of 11 years, the researchers evaluated the association between Decipher scores and participants’ time to distant metastases (DM), prostate cancer-specific mortality (PCSM) and overall survival (OS).

Results demonstrate the Decipher Prostate test was independently prognostic for DM, PCSM and OS, with Decipher high-risk patients experiencing worse outcomes than Decipher low-risk patients on all three endpoints. After adjusting for age, PSA, Gleason score, cT-stage, trial, and randomized treatment arm, the analysis found that the Decipher test scores were independently associated with DM (HR 1.22, 95%CI 1.09-1.36), PCSM (sHR 1.23, 95%CI 1.09-1.39), and OS (HR 1.12, 95%CI 1.05-1.20). Notably, the Decipher test had similar prognostic ability in patients receiving short-term (4 months) or long-term (>24 months) ADT, though the absolute improvement in outcomes varied by Decipher risk. For example, at 10 years, the DM estimates were 31% for short-term vs 20% for long-term ADT in those with higher Decipher Prostate risk scores (an absolute benefit of 11%) but were 7% vs 4% in those with lower Decipher Prostate risk scores (an absolute benefit of 3%).

“This comprehensive analysis of three high-quality, randomized Phase 3 studies demonstrates that the Decipher Prostate Genomic Classifier provides information that can meaningfully impact clinical care for men with prostate cancer,” said Elai Davicioni, Ph.D., Veracyte’s medical director for Urology. “Rigorous analyses and data like these are why we believe the Decipher Prostate test was given ‘Level 1’ evidence status in the NCCN’s most recent prostate cancer guidelines - the only gene-expression test to receive such designation. We believe the new data generated by Dr. Nguyen and colleagues could help physicians considering various treatment options for men with high-risk disease and who desire to tailor the duration and intensity of hormonal therapy for their patients on an individual basis.”

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company whose vision is to transform 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 test can help to more accurately prognosticate patient outcomes, even within a high-risk group, to better personalize care; that the Decipher Prostate Genomic Classifier can help physicians consider treatment options for men with high-risk disease and help tailor duration and intensity of hormonal therapies for patients

on an individual basis; and that the Decipher Prostate Genomic Classifier can improve risk stratification among men with clinically high-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 on February 28, 2022, and our Quarterly Report on Form 10-Q filed for the three months ended September 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.

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