New Data from Phase 3 Trial Further Validate Prognostic Value of Veracyte's Decipher Prostate Genomic Classifier

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Findings presented at the 2023 ASTRO Annual Meeting expand substantial body of evidence demonstrating Decipher Prostate test's ability to help inform prostate cancer treatment decisions.

Additional study suggests level of evidence supporting commercially available genomic classifiers should drive utilization.

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 4, 2023-- Veracyte, Inc. (Nasdaq: VCYT) today announced that new data from a large, randomized phase 3 trial reinforce the value of the Decipher Prostate Genomic Classifier in helping physicians make more informed treatment decisions for their patients with prostate cancer. The findings, presented at the 2023 American Society for Radiation Oncology (ASTRO) Annual Meeting, suggest that the Decipher Prostate test can categorize more accurately risk of patients with clinically high-risk disease to help inform appropriate treatment.

Data from a second study presented at ASTRO 2023 reveal there is minimal to moderate risk-score correlation between the gene expression signatures of three commercially available genomic classifiers, including the Decipher Prostate test. The study authors suggest that, given the lack of correlation seen in the cross-comparison, the level of evidence supporting each genomic test, per nationally recognized consensus guidelines, should drive utilization.

"The findings presented at ASTRO 2023 add to the large body of evidence, which now includes 12 phase 3 randomized trials, demonstrating the Decipher Prostate classifier's performance as a tool to help guide therapeutic decisions in prostate cancer," said Elai Davicioni, Ph.D., Veracyte's medical director for Urology. "Furthermore, they reinforce that the substantial level of evidence supporting the Decipher Prostate test can help guide its selection and utilization for patients with prostate cancer."

The first study assessed the prognostic performance of the Decipher Prostate test among clinically high-risk patients with localized prostate cancer from the phase 3, randomized NRG RTOG 0521 clinical trial, who received radiation and two years of androgen deprivation therapy (ADT) with or without docetaxel chemotherapy. Researchers generated Decipher Prostate test scores using biopsy samples from 183 patients, who were followed for a median of 9.9 years.

Results show that only the Decipher Prostate risk score was independently associated with metastasis-free survival (MFS; HR 1.12, 95% CI) and distant metastasis (DM; sHR 1.22, 95% CI), compared to standard risk factors including Gleason score, T-stage and prostate-specific antigen (PSA) level. Additionally, patients with higher-risk Decipher Prostate genomic scores had worse DM (sHR 2.82, 95% CI) compared to those with lower-risk scores. Cumulative DM at 10 years was 27% for those with higher-risk Decipher test scores vs. 9% for those with lower-risk Decipher test scores (95% CI).

"This study reinforces the ability of the Decipher Prostate classifier to improve risk stratification in high-risk prostate cancer, and thereby support more informed, personalized treatment decisions for these patients," said Phuoc T. Tran, M.D., Ph.D., professor and vice chair for research of Radiation Oncology at the University of Maryland School of Medicine, and co-senior investigator for the study.

In the second study, researchers sought to determine whether risk-score correlation between three commercially available gene expression signatures, including the Decipher Prostate Genomic Classifier, which has the highest level of evidence according to clinical practice guidelines, is strong enough to use the three tests interchangeably. Signature scores for the tests were compared in biopsy samples from over 50,000 patients with localized prostate cancer. The results show that there is a minimal to moderate level of correlation between the three gene expression signatures.

"The poor correlation we observed between the three risk scores suggests that these tests may not be used interchangeably, and clinicians should base utilization on the levels of evidence supporting them," 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.

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 test can help guide its selection and utilization for patients with prostate cancer; and the Decipher Prostate classifier has the ability to improve risk stratification in high-risk prostate cancer, and thereby support more informed, personalized treatment decisions for patients. 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 June 30, 2023. 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.

Decipher Prostate is available in the US as part of Veracyte's CLIA-validated laboratory developed test (LDT) service. This test has not been cleared or approved by the FDA. Veracyte, the Veracyte logo and Decipher are registered trademarks of Veracyte, Inc. and its subsidiaries in the U.S. and selected countries.

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