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New Data Reinforce Ability of Veracyte's Decipher Prostate Genomic Classifier To Help Identify Prostate Cancer Patients Who Would Benefit from Treatment Intensification

Findings published in European Urology Oncology suggest genomic classifier scores are highly correlated with PSMA PET upstaging of prostate cancer in those with high-risk and very high-risk disease

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 17, 2023-- [Veracyte, Inc.](#) (Nasdaq: VCYT) announced that new data published in [European Urology Oncology](#) suggest the Decipher Prostate Genomic Classifier could help identify prostate cancer patients who have micrometastatic disease (difficult-to-detect tumor cells that extend beyond the prostate) and who may therefore benefit from systemic treatment intensification. The data show that, in men with high-risk and very high-risk disease, Decipher Prostate scores are highly correlated with upstaging predictions made by a clinical algorithm shown to predict prostate-specific membrane antigen (PSMA) positron emission tomography (PET) positivity.

"Prostate cancer patients with clinically high-risk and very high-risk disease are prone to treatment failure due to micrometastatic disease that was not detected at the time of initial presentation, so it is imperative that we have tools to accurately identify these patients and intensify their treatment accordingly," said Amar U. Kishan, vice chair of Clinical and Translational Research and chief of the Genitourinary Oncology Service, UCLA Jonsson Comprehensive Cancer Center, and an investigator for the study. "Our findings suggest that a high Decipher Prostate score is highly correlated with the risk of having disease outside the prostate identified on advanced molecular imaging. These patients are likely to benefit from upfront systemic treatment intensification. Ongoing clinical trials are designed to prove this."

The 22-gene Decipher Prostate Genomic Classifier provides a score ranging from 0 to 1, categorized as low (<0.45), intermediate (0.45-0.60) and high risk (>0.60) of metastasis. It is the most validated prognostic biomarker for identifying metastatic disease risk among individuals with prostate cancer to help determine who may benefit from treatment intensification. It is currently being evaluated for its role as a predictive biomarker to guide systemic therapy intensification or deintensification in two large, Phase 3 clinical trials (NRG-GU009, NRG-GU010).

In the current study, researchers sought to quantify the association between the risk of upstaging on PSMA PET using a validated clinical algorithm for PSMA PET positivity developed by researchers at UCLA, and the Decipher Prostate score. Using data from 4,625 prostate cancer patients who met the criteria for NCCN high-risk or very high-risk disease or met the high-risk criteria for the STAMPEDE clinical trial, they calculated the probability of upstaging on PSMA PET using the established, validated clinical nomogram, and correlated this risk and individual patients' Decipher Prostate scores.

The researchers found that there was a significant correlation between patients' Decipher Prostate scores and the risk of upstaging on PSMA PET, and that high Decipher scores were especially enriched in patients at the highest risk of harboring disease outside their prostate. Accordingly, these patients would be more likely to benefit from systemic treatment intensification as compared to local therapy.

"These findings reinforce the evidence supporting the Decipher Prostate test's ability to help inform treatment decision-making at initial prostate cancer diagnosis. We look forward to long-term data from ongoing, prospective trials such as NRG-GU009 to help verify the prognostic and predictive power of the Decipher Prostate test to guide treatment intensification or deintensification in patients with high-risk prostate cancer," 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 could help identify prostate cancer patients who have micrometastatic disease and who may therefore benefit from systemic treatment intensification. 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 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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