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Study Published in JNCI Cancer Spectrum Demonstrates Real-World Utility of Veracyte's Decipher Prostate Genomic Classifier in Prostate Cancer Treatment

Clinical utility study findings based on analysis of the National Cancer Institute's SEER database

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 1, 2023-- [Veracyte, Inc.](#) (Nasdaq: VCYT) announced the publication of a large, real-world study reinforcing the Decipher Prostate Genomic Classifier's ability to guide personalized treatment approaches for men with prostate cancer. The study utilized data from the first linkage of prostate cancer cases reported by central cancer registries participating in the Surveillance, Epidemiology, and End Results (SEER) Program, with Decipher test results. SEER is a population-based cancer registry supported by the National Cancer Institute (NCI). The findings appear online in [JNCI Cancer Spectrum](#).

In the U.S., an estimated 288,300 men are expected to be diagnosed with prostate cancer in 2023 and 34,700 men are expected to die from the disease.^[1] Treatment for prostate cancer is primarily selected based on clinical risk factors such as Gleason score, clinical stage and prostate-specific antigen (PSA). Clinical factors alone, however, do not always reflect the true biology of the tumor, which can lead to over- or under-treatment of patients with prostate cancer. The Decipher Prostate test molecularly assesses the likelihood of a patient's cancer metastasizing within the next five years. Armed with this information, a physician can recommend tailored treatment plans, including no treatment, less intensive treatment or earlier, more intensive interventions.

"Validation from multiple randomized trials has consistently demonstrated the prognostic performance of the Decipher 22-gene expression test," said Daniel Spratt, M.D., chair of the Department of Radiation Oncology at UH Cleveland Medical Center. "This study builds upon this with real-world data of how the test is being used in a population sample and demonstrates how we are moving toward the goal of personalized therapy. Patients with a low Decipher score, indicating a better prognosis, can be guided towards treatment de-escalation, and those with higher Decipher scores, indicating a worse prognosis, can be guided towards appropriate treatment."

The study analyzed data from 8,297 patients in the SEER registry who received a primary prostate cancer diagnosis from 2010 to 2018 and underwent Decipher Prostate testing. Researchers evaluated the association between the patients' Decipher scores (range 0-1) and risk groups (low, intermediate and high), and the use of active surveillance and watchful waiting (AS/WW) as well as adverse pathology at the time of radical prostatectomy (RP).

The results demonstrated that AS/WW was highest among subjects with low-risk Decipher biopsy results (41%), compared to those who had intermediate-risk (27%) or high-risk (11%) scores. Among subjects with clinically low-risk prostate cancer, 65% of those with low-risk Decipher results were managed with AS/WW. Among patients classified as NCCN low or favorable intermediate risk, higher Decipher risk was associated with greater use of local therapy and nearly three times the odds of harboring adverse pathology compared to those with low Decipher risk. The use of prostatectomy and radiotherapy increased with higher Decipher risk groups. For example, prostatectomy was used in 22% of low-, 30% of intermediate-, and 39% of high-risk Decipher patients and radiotherapy was used in 16% of low-, 24% of intermediate-, and 35% of high-risk Decipher patients. The study also found a significant association between higher Decipher risks groups and the use of post-operative radiotherapy.

"This study is further evidence that the Decipher Prostate test provides valuable clinical information to physicians and their patients with prostate cancer. In contemporary practice, physicians treat patients with higher-risk Decipher scores more aggressively, and patients with lower-risk Decipher scores more conservatively," said Elai Davicioni, Ph.D., Veracyte's medical director for Urology. "This is the first large national database study in ongoing collaborations with the National Cancer Institute SEER program and represents our sustained commitment to research and real-world evidence development."

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's can guide personalized treatment approaches for men with prostate cancer; the Decipher Prostate test can assess the likelihood of a patient's cancer metastasizing within the next five years which may assist a physician to recommend tailored treatment plans, including no treatment, less intensive treatment or earlier, more intensive interventions; and that patients with a low Decipher score indicate a better prognosis, can be guided towards treatment de-escalation, and those with higher Decipher scores, indicating a worse prognosis, can be guided towards appropriate treatment. 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 March 31, 2023. Copies of these documents, when available, may be found in the Investors section of our website at . 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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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.

1. American Cancer Society. Cancer Facts & Figures 2023.

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