New Data Presented at ESMO 2024 Show that Veracyte's Decipher Prostate Test Predicts Chemotherapy Benefit in Patients with Metastatic Prostate Cancer

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Findings are from ancillary study of phase 3 STAMPEDE trial

Data support company's plan to expand Decipher Prostate test to patients with metastatic disease

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 15, 2024-- Veracyte, Inc. (Nasdaq: VCYT), a leading cancer diagnostics company, today announced that new data from a phase 3 trial of the multi-center, randomized STAMPEDE clinical trial show that its Decipher Prostate Genomic Classifier is prognostic for clinical outcomes and predicts benefit from docetaxel in patients with metastatic prostate cancer. The findings were presented today (Presentation #15960) at the European Society for Medical Oncology (ESMO) 2024 Congress in Barcelona. These findings support Veracyte's plan to expand use of the Decipher Prostate test – currently widely used to guide care for localized prostate cancer – to patients with metastatic disease.

Prostate cancer accounts for a fifth (approximately 375,000) of all male cancer-related deaths globally and the number is expected to double over the next two decades.[1] In the United States, it is the second-leading cause of cancer deaths among men, with more than 35,000 men expected to die of the disease in 2025.[2] Most prostate cancer deaths occur in patients who first presented with advanced or metastatic disease.

"For patients with metastatic prostate cancer, adding the chemotherapy docetaxel to standard-of-care androgen deprivation therapy (ADT) can increase survival. However, patient response varies and today physicians have limited tools for identifying who will likely benefit from the drug and who won't," said Gerhardt Attard, M.D., Ph.D., Professor and John Black Charitable Foundation Endowed Chair in Urological Cancer Research at University College London and STAMPEDE trial co-investigator. "Our findings are important because they show that the Decipher Prostate test can help clinicians better distinguish patients with metastatic prostate cancer who receive the greatest benefit from docetaxel from those who don't and may therefore avoid unnecessary toxicity."

In the new study, researchers analyzed data for 1,523 patients with advanced or metastatic prostate cancer who were followed in the STAMPEDE trial for a median of 14 years. They found that higher Decipher Prostate test scores were associated with an increased risk of death in both groups. Additionally, among the 832 patients with metastatic disease, only those with higher Decipher Prostate scores received a significant survival benefit from the addition of docetaxel to ADT. These patients had a 36% reduction in risk of death (HR 0.64, 95% CI, 0.48-0.86) with the addition of docetaxel as compared to those with lower Decipher scores who did not significantly benefit (HR 0.96, 0.71-1.30; interaction p=0.039).

Notably, docetaxel was beneficial in patients with higher Decipher Prostate scores regardless of whether they had high- or low-volume prostate cancer. This is important because current clinical practice favors use of docetaxel in patients with high- but not low-volume disease.

"The Decipher Prostate test's ability to help guide treatment for patients with localized prostate cancer is already proven in dozens of peer-reviewed publications and is the only molecular test to achieve 'Level 1B' evidence status in the most recent NCCN® Guidelines* for prostate cancer," said Elai Davicioni, Ph.D., Veracyte's medical director for Urology. "These new phase 3 data from the STAMPEDE trial now further prove the performance and utility of our test in patients with metastatic prostate cancer. We believe our test can have a tremendous positive impact on care for these patients."

Veracyte expects to begin offering the Decipher Prostate test to patients with metastatic prostate cancer in early 2025, after its anticipated reimbursement by Medicare. MolDX, a program that establishes Medicare coverage for advanced molecular diagnostic tests, recently issued a local coverage determination for molecular testing in patients with metastatic prostate cancer, providing what Veracyte believes is a pathway to coverage for its test.

"We are excited about the new Decipher Prostate data presented at ESMO and the opportunity to advance cancer care for even more patients," said Marc Stapley, Veracyte's chief executive officer. "These important advances clearly demonstrate the power of our Veracyte Diagnostics Platform, which delivers high-performing cancer tests and a powerful evidence-generation engine. Ultimately, this novel approach helps drive widespread test reimbursement and adoption, along with new insights to support our pipeline. This includes expanding the use of Decipher Prostate now to patients across the prostate cancer continuum, from those who are low risk and can benefit from active surveillance, to those who are metastatic and can benefit from chemotherapy."

About Decipher Prostate

The Decipher Prostate Genomic Classifier is a 22-gene test, developed using RNA whole-transcriptome analysis and machine learning, that helps inform treatment decisions for patients with prostate cancer. The test is performed on biopsy or surgically resected samples and provides an accurate risk of developing metastasis with standard treatment. Armed with this information, physicians can better personalize their patients' care and may recommend less-intensive options for those at lower risk or earlier, more-intensive treatment for those at higher risk of metastasis. The Decipher Prostate test has been validated in more than 80 published studies involving more than 100,000 patients. More information about the Decipher Prostate test can be found here.

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 Veracyte Diagnostics Platform delivers high-performing cancer tests that are fueled by broad genomic and clinical data, deep bioinformatic and AI capabilities, and a powerful evidence-generation engine, which ultimately drives durable reimbursement and guideline inclusion for our tests, along with new insights to support continued innovation and pipeline development. For more information, please visit www.veracyte.com and follow the company on X (formerly Twitter) at @veracyte.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to our statements related to the potential for the Decipher Prostate test to provide better prognostic information for patients with prostate cancer and guide treatment; the potential pathway to test reimbursement and adoption; and that the Decipher Prostate test can have a positive impact on patient care and advance cancer care. Forward-looking statements can be identified by words such as: “appears,” “anticipate,” “intend,” “plan,” “expect,” “believe,” “should,” “may,” “will,” “enable,” “positioned,” “offers,” “designed,” "ultimately," and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to the potential impact the Decipher Prostate test can have on scientific advancements in prostate cancer and, in turn, 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 29, 2024 and our subsequent Quarterly Reports on Form 10-Q. 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.

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[1] James, N. D. *et al.* The Lancet Commission on prostate cancer: planning for the surge in cases. *Lancet* 403, 1683–1722 (2024).

[2] American Cancer Society. *Cancer Facts & Figures 2024*. Atlanta: American Cancer Society; 2024.

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