New Data Demonstrate Accuracy of Veracyte's Whole-Genome Sequencing-Based MRD Testing Platform for Muscle-Invasive Bladder Cancer

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Findings from TOMBOLA Trial Were Presented at EAU25

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 25, 2025-- Veracyte, Inc. (Nasdaq: VCYT), a leading cancer diagnostics company, today announced new data showing that its whole-genome sequencing (WGS)-based platform for minimal residual disease (MRD) testing detected cancer in patients treated for muscle-invasive bladder cancer (MIBC) with more accuracy than ddPCR-based blood testing and earlier compared to standard imaging. The findings, from the large, independent, multicenter, interventional TOMBOLA trial (NCT04138628), were shared in an oral presentation at the 40th Annual European Association of Urology Congress (EAU25) in Madrid by Iver Nordentoft, Ph.D., Aarhus University (Abstract A0162: "Comparison of ctDNA detection methods for monitoring minimal residual disease in patients with bladder cancer: Insights from the TOMBOLA Trial").

The new study involved 100 patients enrolled in the TOMBOLA trial who had MIBC and were undergoing standard-of-care neoadjuvant chemotherapy (NAC) and radical cystectomy (RC). Their blood samples were evaluated for circulating tumor DNA (ctDNA) using both ddPCR-based and Veracyte's WGS-based MRD testing platform to detect disease recurrence. Patients also underwent imaging. At the 6-month milestone, in comparison to ddPCR, the Veracyte MRD testing platform had an equivalent and outstanding negative predictive value (95.9% Veracyte MRD vs. 96.2% ddPCR) for cancer recurrence, while having a higher specificity (88% Veracyte MRD vs. 62% ddPCR). Longer follow-up is required to determine the clinical impact of these results. The findings also showed that the Veracyte MRD testing platform detected cancer recurrence a median of 93 days sooner than imaging. In the ongoing trial, ctDNA-positive patients are treated with immunotherapy and followed for clinical response.

"Up to half of patients with muscle-invasive bladder cancer experience recurrence within two years of initial treatment, and using ctDNA status to guide oncological treatment would spare some patients from unnecessary treatments," said Lars Dyrskjøt Andersen, Ph.D., professor in the Department of Clinical Medicine and Department of Molecular Medicine at Aarhus University in Denmark and principal investigator of the TOMBOLA trial. "ctDNA testing using ddPCR has demonstrated promise for MRD detection, but it has inherent limitations that may impede its clinical use, particularly on a large scale. Our findings show that Veracyte's whole-genome sequencing approach to MRD testing demonstrates high accuracy and may improve overall clinical utility, compared to ddPCR."

Veracyte's MRD testing platform utilizes a combination of whole-genome sequencing and artificial intelligence (AI) to provide fast and accurate detection of residual cancer in a patient's blood sample. This approach requires less blood and offers faster results, compared to ctDNA testing that uses bespoke panels, enabling earlier detection and improved outcomes. Veracyte's MRD testing platform characterizes the complete set of cancer mutations in the tumor tissue sample and blood to establish a patient-specific, landmark genomic signature. It then uses whole-genome sequencing and AI to detect that signature in subsequent blood samples, indicating that cancer is present, and to track tumor progression throughout the patient's treatment and follow-up care. Veracyte plans to launch its first MRD test in muscle-invasive bladder cancer in the first half of 2026, with other cancer indications to follow.

"The new data presented at EAU25 reinforce the power of the Veracyte Diagnostics Platform, which is at the core of all of our tests and will now enable us to expand into MRD testing in a clinically meaningful way," said Philip Febbo, M.D., Veracyte's chief scientific officer and chief medical officer. "With our first MRD test in muscle-invasive bladder cancer, we are excited to expand our test offerings along the care continuum in urologic cancers where our Decipher tests are widely used and trusted by clinicians to help guide prognosis and treatment decisions."

In addition to the new data for Veracyte's MRD testing platform, seven abstracts focused on the company's Decipher Prostate and Decipher Bladder tests were presented at EAU25. More information can be found at the EAU25 website.

About Decipher Bladder

The Decipher Bladder Genomic Classifier is a 219-gene test, developed using RNA whole-transcriptome analysis and machine learning, that is designed for use in patients following bladder cancer diagnosis who face questions regarding treatment intensity. The test classifies bladder tumors into five molecular subtypes, each having distinct tumor biology and potential clinical implications. This information can help physicians and their patients better understand the degree of benefit that would likely be gained from neoadjuvant chemotherapy and/or the likelihood of harboring non-organ-confined disease at time of surgery, respectively. More information about the Decipher Bladder test can be found here.

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's performance and clinical utility has been demonstrated in over 85 studies involving more than 200,000 patients. It is the only gene expression test to achieve "Level IB" evidence status and inclusion in the risk-stratification table in the most recent NCCN® Guidelines* for prostate cancer. 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 power of Veracyte's whole-genome approach, which will now enable us to expand into MRD testing in a clinically meaningful way; our plans to launch our first MRD test in muscle-invasive bladder cancer in the first half of 2026, with other cancer indications to follow; and that Veracyte's whole-genome sequencing approach to MRD testing may improve overall clinical utility, compared to ddPCR. 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 Veracyte Diagnostics Platform can have on scientific advancements in cancer and, in turn, patient care. 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, 2025. 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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