New Data at ASCO GU Show Power of Veracyte's Decipher Tests to Improve Patient Care and Its GRID Tool to Advance Prostate and Bladder Cancer Research

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***Study showing that Decipher GRID-derived PORTOS signature predicts benefit from dose-escalated radiation therapy also published in* Annals of Oncology**

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 14, 2025-- Veracyte, Inc. (Nasdaq: VCYT), a leading cancer diagnostics company, today announced that new data presented at the 2025 ASCO Genitourinary Cancers Symposium (ASCO GU) demonstrate the performance and clinical utility of its Decipher Prostate and Decipher Bladder tests to help guide treatment for patients with prostate and bladder cancer. Presented findings also show that the company's Decipher GRID (Genomic Resource for Intelligent Discovery) research tool is enabling new data-based insights that in the future may help further advance personalized cancer care. The findings are from among 17 Decipher-focused abstracts being presented at the conference this week in San Francisco, as well as a new paper published in *Annals of Oncology.*

"The breadth and depth of Decipher-focused data presented at the ASCO GU Symposium reinforce the widespread impact our Decipher tests are having on clinical care, as well as on research into the molecular underpinnings of prostate and bladder cancers," said Elai Davicioni, Ph.D., Veracyte's medical director for Urology. "They also demonstrate Veracyte's commitment to clinical rigor and evidence development. We are grateful for our ongoing collaborations with leading clinician-researchers, which are enabling us to continue driving innovation that can further help patients."

Key findings presented at the ASCO GU Symposium are:

Poster (Abstract #399): Decipher Score as a Predictor of Response to Treatment Intensification in the NRG Oncology-RTOG 0534 (SPPORT) Phase III Randomized Post-Prostatectomy Salvage Radiotherapy Trial. Presented by Alan Pollack, M.D., Ph.D., University of Miami Health System.

This study found that the Decipher Prostate Genomic Classifier may inform treatment-intensification strategies for patients undergoing salvage radiotherapy by identifying those who will benefit from pelvic nodal radiation. The findings are from a post-hoc analysis of the NRG Oncology/RTOG 0534 (SPPORT) Phase 3, randomized trial. Decipher Prostate test results were obtained for 709 patients who experienced biochemical recurrence following prostatectomy and were allocated to three treatment study arms: 1.) prostate bed radiation therapy alone (PBRT); 2.) PBRT and short-term androgen deprivation therapy (STADT); or 3.) PBRT, STADT and pelvic lymph node radiation therapy (PLNRT). They found that patients with high Decipher Prostate scores received greater benefit from the addition of PLNRT and STADT to PBRT, compared to those with low genomic test scores.

"The addition of pelvic node radiotherapy to PBRT and short-term ADT is becoming more frequently used for patients with high-risk prostate cancer undergoing salvage radiation," said Dr. Davicioni, an author on the study. "Accurately determining which patients are likely to benefit from this strategy, however, can be challenging but is especially important given its additional toxicity and potential side effects. Our findings show that Decipher Prostate test results can provide physicians with important information to help guide treatment decision-making with their patients."

Poster (Abstract #831): A non-coding RNA based classifier for favorable outcomes in clinically organ confined bladder cancer. Presented by Yair Lotan, M.D., UT Southwestern Medical Center.

In this study, researchers demonstrated that the Decipher Bladder Genomic Subtyping Classifier accurately identified patients whose bladder cancer was less aggressive, based on their cancer's molecular subtype. The study involved 226 patients with high-grade, clinically organ-confined bladder cancer who subsequently underwent radical cystectomy without any neoadjuvant therapy. The researchers found that patients with the luminal favorable bladder cancer subtype, compared to those without it, had significantly lower likelihood of being upstaged to T3+ disease (OR 0.32, 95% CI 0.12-0.82; P= 0.02) or to any upstaging (OR 0.41, 95% CI 0.20-0.83; P=0.01). They also found that the luminal favorable subtype was significantly associated with better overall survival (HR 0.33, 95% CI 0.15-0.74; P=0.007).

"Accurate clinical staging in bladder cancer can be challenging, limiting clinicians' ability to guide treatment decisions for their patients," said Dr. Lotan. "Our findings suggest that molecular subtyping information provided by the Decipher Bladder test can help physicians better identify which patients have less-aggressive bladder cancer and may not require treatment intensification."

Oral Presentation (Abstract #308): Gene signature predictor of dose-response to prostate radiation: validation of PORTOS in phase III trials. Presented by Shuang Zhao, M.D., University of Wisconsin-Madison.

This study's oral presentation at the ASCO GU Symposium also corresponded with its publication in *Annals of Oncology*. The findings demonstrate that PORTOS (Post-Operative Radiation Therapy Outcomes Score), a genomic signature developed using Veracyte's Decipher GRID research tool, predicts which patients with prostate cancer are likely to benefit from differing dosages of salvage and definitive radiation therapy. The findings are from post-hoc analyses of the SAKK 09/10 and NRG Oncology/RTOG 0126 Phase 3, randomized clinical trials.

Among the 226 patients evaluated from the SAKK 09/10 trial, those with higher PORTOS scores were significantly more likely to benefit from dose-increased (70 Gy vs. 64 Gy) salvage radiotherapy, compared to those with lower PORTOS scores. Additionally, among 215 patients undergoing definitive radiotherapy in the NRG Oncology/RTOG 0126 trial, those with higher PORTOS scores were more likely to benefit from dose escalation (79.2 Gy vs. 70.2 Gy), compared to those with lower PORTOS scores. An analysis using the whole-transcriptome-based Decipher GRID research tool's database showed that there were no strong associations between the PORTOS signature and clinicopathologic variables such as race, PSA levels, clinical stage, grade group or NCCN risk status.

"Physicians are currently limited in their tools for determining which patients with prostate cancer will benefit from dose-escalated radiation therapy. Our findings, derived from two Phase 3, randomized trials, suggest that the research-based PORTOS signature has potential to be a useful clinical tool to help inform important radiation treatment decisions for patients following a prostate cancer diagnosis or who are experiencing biochemical recurrence," said Dr. Zhao, who also helped develop the PORTOS signature.

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 many dozens of published studies involving more than 100,000 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 Decipher Bladder

The Decipher Bladder Genomic Subtyping 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 GRID

The Decipher GRID database includes more than 200,000 whole-transcriptome profiles from patients with urologic cancers and is used by Veracyte and its partners to contribute to continued research and help advance understanding of prostate and other urologic cancers. GRID-derived information is available on a Research Use Only basis. More information about Decipher GRID 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 LinkedIn and 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 Decipher Prostate and Decipher Bladder tests to help guide treatment for patients with prostate and bladder cancer and Decipher GRID to enable new data-based insights that may in the future help further advance personalized cancer care; that the Decipher Prostate Genomic Classifier may inform treatment-intensification strategies for patients undergoing salvage radiotherapy by identifying those who will benefit from pelvic nodal radiation; that the findings suggest that the Decipher Bladder test can help physicians better identify which patients have less-aggressive bladder cancer and may not require treatment intensification; and that the PORTOS signature has potential to be a useful clinical tool to help inform important radiation treatment decisions for patients following a prostate cancer diagnosis or who are experiencing biochemical recurrence. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "estimate," "plan," "project," "expect," "believe," "should," "may," "could," "would," "will," "potentially," "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. 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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