14 Studies Presented at AUA 2024 Show Decipher Tests' Ability to Help Personalize Care for Prostate and Bladder Cancer Patients and Advance Disease Understanding

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Large number of abstracts also showcases power of the Veracyte Diagnostics Platform

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 6, 2024-- Veracyte, Inc. (Nasdaq: VCYT), a leading cancer diagnostics company, today announced that data from 14 presentations at AUA 2024, the annual meeting of the American Urological Association, show that the Decipher Prostate and Decipher Bladder Genomic Classifiers provide better prognostic information for patients with prostate and bladder cancer, compared to standard approaches. They also show that the research-use-only Decipher GRID (Genomic Resource for Intelligent Discovery) tool is helping to advance scientific understanding of these diseases. The findings were presented during the conference taking place May 3-6 in San Antonio.

"The large amount of data presented at AUA 2024 reinforces Veracyte's commitment to building rigorous evidence that demonstrates our tests' performance and clinical utility," said Elai Davicioni, Ph.D., Veracyte's medical director for Urology. "Further, our whole-transcriptome approach to testing provides an incredible amount of data that we are pleased to share with the research community through Decipher GRID to help advance understanding of urologic cancers and ultimately improve patient outcomes."

Studies showing the Decipher Prostate test's ability to better inform prostate cancer treatment include:

- **Poster MP41-09: Genomic Signatures Associated with Adverse Pathologic Features at Radical Prostatectomy Among Active Surveillance Eligible Men. Presented by Eric Li, M.D., Northwestern University.**

  Summary: The Decipher Prostate Genomic Classifier is associated with adverse pathology in patients eligible for Active Surveillance (AS) who were treated with radical prostatectomy (RP). The findings suggest the Decipher test may be able to identify patients at increased risk of harboring higher grade and non-organ confined disease who may not be ideal candidates for AS.

  "Despite having similar clinical features at diagnosis, our study suggests that AS-eligible prostate cancer patients have a spectrum of risk for occult adverse pathology that can be elucidated at the level of gene expression," said Ashley Ross, M.D., Ph.D., clinical director for the Polsky Urological Oncology Center at Northwestern University and principal investigator on the study. "Our results suggest that use of the Decipher Prostate test may help clinicians better stratify risk among patients eligible for AS, which may ultimately help reduce under- and over-treatment."

- **Poster MP41-14: High Decipher scores define the subgroup most at risk of metastatic progression among patients with lower-grade tumors classified as NCCN high-risk based on elevated prostate-specific antigen level alone. Presented by David Han, M.D., Columbia University Irving Medical Center.**

  Summary: Despite harboring favorable, lower grade (Grade Group 1 or 2) organ-confined disease, patients with a prostate-specific antigen (PSA) level of >20 ng/mL are currently classified by practice guidelines as "high risk". In a cohort of 453 patients with long-term outcomes, the Decipher Prostate test score better predicted the development of distant metastases than PSA. These results provide further evidence that a higher Decipher score is a more accurate risk factor than PSA in patients with otherwise favorable disease.

- **Poster MP49-09: Decipher Predicts Clinically Significant Upgrading on Final Radical Prostatectomy Pathology. Presented by John Sheng, M.D., Washington University School of Medicine in St. Louis.**

  Summary: A large registry (n=760) from prospective clinical use of Decipher Prostate and multiparametric prostate MRI (mpMRI) at diagnosis was examined to determine factors significantly associated with high-grade disease at radical prostatectomy (RP). In the subset with low- or intermediate-grade prostate cancer at initial biopsy only Decipher and grade group, but not mpMRI PIRADS or baseline PSA, predicted high-risk disease at final pathology after RP.

- **Podium Presentation PD42-03: Understanding Population-Wide Genomic Risk Distribution and Integrating Clinical-Genomic Risk for Prognostication in Prostate Cancer. Presented by Udit Singhal, M.D., University of Michigan.**

  Summary: The International Staging Collaboration for Prostate Cancer (STAR-CAP) is a highly validated prognostic clinical risk staging system. In an analysis of 52,565 patients from the state-wide Michigan Urological Surgery Improvement Collaborative (MUSIC) and the nation-wide Decipher GRID database, researchers found wide variation of Decipher Prostate Genomic Classifier scores within STAR-CAP risk groups. Overall, they found Decipher testing augmented by at least one STAR-CAP stage both upstaging for about 25% and down-staging for nearly 50% of cases, suggesting that integration of genomic with advanced clinicopathologic staging systems may lead to further improvements to risk stratification across the clinical spectrum of localized disease.

The following study demonstrates the Decipher Bladder test's utility in informing treatment decisions for patients with bladder cancer:

- **Poster MP15-07: Molecular subtyping for predicting non-organ confined disease and survival outcomes after radical cystectomy in clinical high-grade T1 and T2 bladder cancer patients. Presented by Yair Lotan, M.D., UT Southwestern Medical Center.**

  Summary: Clinical staging in bladder cancer commonly underestimates the true disease stage as many patients are upstaged to non-organ confined (NOC) disease (pT3+ and/or N+) at radical cystectomy (RC). This multi-center study of 200 patients validates prior findings, further demonstrating the utility of the Decipher Bladder Genomic Subtyping Classifier (GSC) for predicting upstaging and outcomes in a cohort of patients with clinical T1 or T2 bladder cancer treated with radical cystectomy but without neoadjuvant therapy.

Additional studies used the RUO Decipher GRID tool to explore prostate and bladder cancer topics that include: which patients are likely to benefit from specific therapies, racial differences in disease biology, and molecular pathway alterations following treatment.

"The depth and breadth of Decipher-focused data at AUA 2024 underscores the value of our novel Veracyte Diagnostics Platform, which begins with delivering high-performing tests using a comprehensive, whole-transcriptome approach. This fosters additional research, which in turn supports further innovation to help more patients," said Phillip Febbo, M.D., Veracyte's chief scientific officer and chief medical officer.

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, the physician 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 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 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 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: (i) for the Decipher Prostate and Decipher Bladder Genomic Classifiers to provide better prognostic information for patients with prostate and bladder cancer, compared to standard approaches; (ii) for the Decipher GRID research use only tool to contribute to further scientific developments and ultimately patient outcomes; and (iii) for the Veracyte Diagnostics Platform value to support further innovation and help patients. 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 Decipher GRID 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. 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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