



Veracyte Announces that Decipher-Enabled Biomarker Predicts Hormone Therapy Benefit in Men with Recurrent Prostate Cancer

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Findings from the first prospective validation trial for biomarker presented at ASTRO 2025

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 28, 2025-- [Veracyte, Inc.](#) (Nasdaq: VCYT), a leading genomic diagnostics company, announced that new data from the prospective, randomized integral biomarker BALANCE trial (NCT03371719) finds that the PAM50 molecular signature predicts which patients with recurrent prostate cancer benefit from hormone therapy with apalutamide in addition to salvage radiation therapy. The prostate PAM50 biomarker is currently available for Research Use Only on the Decipher GRID (Genomic Resource for Intelligent Discovery) research tool.

The new findings were shared today by Daniel Spratt, M.D., University Hospitals Seidman Cancer Center, Case Western Reserve University, in a podium presentation at ASTRO 2025, the annual meeting of the American Society for Radiation Oncology, being held in San Francisco.

"Our findings mark the first time, to my knowledge, that a predictive biomarker has been validated in a prospective, biomarker-driven, randomized trial in non-metastatic prostate cancer," said Dr. Spratt. "Thus, this is an unprecedented advancement for patients who can be more-precisely selected to receive hormone therapy or forego the treatment and the potential side effects."

For the study, 295 men with recurrent, non-metastatic prostate cancer following prostate-removal surgery were randomly assigned to salvage radiation therapy with a placebo or apalutamide for 6 months. The PAM50 biomarker was a key stratification variable to ensure each arm had a similar proportion of luminal B and non-luminal B subtypes. They were followed for a median of 5 years during which they were evaluated for biochemical failure, which is a rise in levels of prostate-specific antigen (PSA) post treatment—an early sign of salvage therapy failure. Among the 127 men with luminal B molecular subtype tumors (as determined by the PAM50 signature), 72% of those taking apalutamide did not experience biochemical failure, as compared to the 54% rate in the placebo group [HR 0.45 (80% CI 0.29-0.68), p=0.0062]. In the non-luminal B subset, there was no difference between those taking apalutamide versus placebo (70% vs 71%) [HR 0.95 (80% CI 0.65-1.41), p=0.44].

"These results from NRG GU006 represent the highest level of evidence to support routine biomarker testing in recurrent prostate cancer patients planned to receive secondary radiotherapy," Dr. Spratt added. "With such a strong difference in the metastasis-free survival response to hormone therapy between luminal B and non-luminal-B tumors, the use of the predictive PAM50 biomarker is a game changer to help personalize treatment for men with recurrent prostate cancer beyond merely prognostic tools."

The PAM50 signature is the third biomarker—assessed through the whole-transcriptome-based Decipher platform—that a major study has shown predicts benefit from hormone therapy, radiation therapy or chemotherapy. Another trial—[PREDICT-RT](#)—recently completed enrollment two years early and is evaluating the Decipher Prostate test's ability to predict benefit of combined hormone therapy (ADT and apalutamide) concurrent with radiation in patients with high-risk prostate cancer at initial diagnosis.

"Prostate cancer, like all cancers, is a disease of the genome," said Elai Davicioni, Ph.D., Veracyte's medical director for Urology. "Our Decipher GRID tool uniquely enables researchers to better pinpoint adverse molecular features that are associated with poor outcomes. This can ultimately lead to more-personalized care for each patient based on their tumor's unique molecular make-up. We are proud to partner with the world's leading prostate cancer researchers to help uncover insights that can change the trajectory of care for each individual patient and also help deliver the next generation of prostate cancer diagnostics."

The BALANCE trial results are among 9 Decipher-focused abstracts being presented at the ASTRO 2025 conference. More information 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 across the full spectrum of prostate cancer. The test is performed on biopsy or surgically resected samples and conveys the aggressiveness of the cancer. For patients with localized or regional prostate cancer, the Decipher score indicates a patient's risk of metastasis, helping to determine treatment timing and intensity. For patients with metastatic prostate cancer, the Decipher score indicates the likelihood of cancer progression and survival benefit with treatment intensification. Armed with this information, physicians can better personalize their patients' care. The Decipher Prostate test's performance and clinical utility has been demonstrated in over 90 studies involving more than 200,000 patients. It is the only gene expression test to achieve "Level I" 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 or follow us on [LinkedIn](#) or [X \(Twitter\)](#).

About Decipher GRID

The Decipher GRID database includes more than 250,000 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](#).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to our statements regarding the use of the predictive PAM50 biomarker to help personalize treatment for men with recurrent prostate cancer beyond merely prognostic tools and the belief that this is a game changer, and expectations that our Decipher GRID tool uniquely enables researchers to better pinpoint adverse molecular features that are associated with poor outcomes; that this can ultimately lead to more-personalized care for each patient based on their tumor's unique molecular make-up; and that this can help uncover insights that can change the trajectory of care for each individual patient and also help deliver the next generation of prostate cancer diagnostics. 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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