# New Study Shows Veracyte's Decipher Bladder Test Predicts Disease Upstaging in Patients with Bladder Cancer

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***Findings Further Expand Company's Extensive Clinical Evidence In Urologic Cancers***

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 5, 2025-- Veracyte, Inc. (Nasdaq: VCYT), a leading cancer diagnostics company, today announced new data that reinforce the ability of its Decipher Bladder Genomic Subtyping Classifier to help improve staging for patients with bladder cancer, based on their tumors' molecular subtype. The findings, published in *European Urology Open Science*, show that the test can help clinicians better determine which patients are more likely to harbor more aggressive disease than suggested by their initial clinical staging following transurethral resection of bladder tumor (TURBT).

Researchers analyzed data for 226 patients from eight medical centers who underwent radical cystectomy (RC) without neoadjuvant chemotherapy (NAC). The study cohort included 134 patients with high-risk non-muscle-invasive bladder cancer (NMIBC) and 92 patients with muscle-invasive bladder cancer (MIBC) classified as T2, in which the cancer had grown into, but not through, the bladder's muscle layer. Key findings included:

- Following RC without neoadjuvant chemotherapy, pathological upstaging to non-organ-confined disease was observed in 33% of patients (19% for NMIBC and 53% for T2 disease), demonstrating the challenges in bladder cancer clinical staging.
- Using the Decipher Bladder test to determine each tumor's molecular subtype, researchers found that NMIBC patients with non-luminal tumors were more likely to be upstaged to MIBC, compared to those with luminal tumors (51% vs. 32%, multivariable p=0.03).
- Patients with luminal-subtype bladder cancer had better overall survival on multivariable analyses (non-luminal vs. luminal adjusted HR 1.67 [95% CI 1.01-2.78], p=0.05), based on a median follow-up of 33 months.

"Accurate clinical staging in bladder cancer can be challenging, limiting clinicians' ability to guide treatment decisions for their patients," said Yair Lotan, M.D., professor of urology and chief of urologic oncology at UT Southwestern Medical Center and corresponding author on the study. "Our findings suggest that molecular subtyping information provided by the Decipher Bladder test can help clinicians better identify which patients may benefit from more-intensive treatment with neoadjuvant chemotherapy and which will not and can thus avoid its toxicity."

The study comes on the heels of three recent peer-reviewed, published studies[1-3] demonstrating the performance and clinical utility of the Decipher Bladder test and its whole-transcriptome approach. The new publication also builds on Veracyte's extensive body of clinical evidence supporting its molecular tests in urology where its Decipher Prostate Genomic Classifier is the market leader in prostate cancer.

"We are increasing our collaboration efforts with leading clinician-scientists to improve and further personalize bladder cancer care, similar to our approach in prostate cancer which has amassed over 85 publications from analysis of hundreds of thousands of patient transcriptomes," said Elai Davicioni, Ph.D., medical director, Urology, at Veracyte. "This approach is the lynchpin of our Veracyte Diagnostics Platform, which helps facilitate evidence generation, reimbursement and adoption for our tests. It also provides insights that fuel continued innovation, with the overall goal of supporting physicians to deliver better, more-personalized patient care."

**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 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 1B" 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 for the use of the Decipher Bladder Genomic Subtyping Classifier to help clinicians better determine which patients are more likely to harbor more aggressive disease than suggested by their initial clinical staging following transurethral resection of bladder tumor (TURBT) and better identify which patients may benefit from

more-intensive treatment with neoadjuvant chemotherapy and which will not and can thus avoid its toxicity. 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 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] Hwang MW, et al. Upper tract urothelial cancer (UTUC) genomic profiling and correlation regarding benefit of platinum-based chemotherapy. *Explor Target Antitumor Ther.* 2024;5(6):1261-1270.

[2] Reike MJ, Raggi D, Mercinelli C, et al. Distinct Gene Expression Patterns Identify Patients who Relapse After Neoadjuvant Pembrolizumab and Radical Cystectomy in the PURE-01 Study. *Clin Genitourin Cancer*. 2024;22(6):102214. doi:10.1016/j.clgc.2024.102214.

[3] de Jong JJ, et al. A luminal non-coding RNA-based genomic classifier confirms favourable outcomes in patients with clinically organ-confined bladder cancer treated with radical cystectomy. *BJU Int*. Published online November 1, 2024. doi:10.1111/bju.16572.

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