October 13, 2021

New Publication Demonstrates Ability of Veracyte's Decipher Bladder Test to Identify Tumors Most Likely to Respond to Chemotherapy

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 13, 2021-- Veracyte, Inc., (Nasdaq: VCYT) announced today the publication of new data demonstrating that the company's Decipher Bladder genomic classifier accurately identifies bladder tumors that are most likely to respond to chemotherapy prior to radical cystectomy. These findings could ultimately help physicians optimize treatment planning for their patients with bladder cancer based on their tumor subtype biology. The peer-reviewed paper appears online today in *The Journal of Urology*.

Patients diagnosed with non-metastatic muscle-invasive bladder cancer (MIBC) often undergo neoadjuvant chemotherapy (NAC) prior to standard-of-care radical cystectomy, even though the absolute survival benefit associated with the addition of NAC to radical cystectomy is 5-10%. Until recently, there was no reliable way to determine which MIBC tumors would – or would not – respond to chemotherapy. Molecular subtyping with the Decipher Bladder genomic classifier has shown that biological differences in MIBC are strongly associated with chemotherapy response.

"Our findings are among the first to show the clinical utility of implementing molecular subtyping in order to identify patients for whom NAC is most likely to confer significant benefit," said Yair Lotan, MD, professor of urology and chief of urologic oncology at UT Southwestern Medical Center, and the paper's lead author. "This study represents meaningful progress in clinically validating biomarkers that are associated with chemotherapy response in patients with MIBC, and it offers hope that we will be able to better manage these patients in the future by accurately selecting those most likely to benefit from additional treatment."

In this multicenter retrospective study, scientists evaluated the use of the Decipher Bladder genomic classifier in a cohort of 601 patients. After three years, patients with classifier-identified luminal tumors (37% of the study population) experienced no additional benefit to overall survival (OS) from receiving NAC prior to radical cystectomy (63% OS with NAC and 65% OS without). However, those patients whose tumors were classified as non-luminal (63% of the study population) experienced a significant benefit from the addition of NAC, with 10% greater overall survival after three years as compared to patients who were treated with cystectomy alone (71% vs. 61%).

"We are pleased that our Decipher Bladder genomic classifier performed so well in this broad study," said Elai Davicioni, Ph.D., Veracyte's senior vice president of scientific and clinical operations, Urologic Cancers. "We look forward to further validating the test to encourage its routine clinical use for patients diagnosed with MIBC."

The Decipher Bladder test is supported by multiple peer-reviewed clinical studies demonstrating its ability to identify which patients have a higher risk of upstaging to non-organ confined disease at surgery and which patients may benefit the most from neoadjuvant therapy. The test also can be used to identify neuroendocrine-like and immune-infiltrated subtypes, which may have implications for future therapeutic strategies. In June 2021, Veracyte announced that Decipher Bladder had become the first molecular subtyping test to gain Medicare coverage to inform treatment for individuals with bladder cancer.

About Decipher Bladder

Decipher Bladder is a genomic test that measures the molecular profile of bladder cancer using gene expression analysis from transurethral resected bladder tumor specimens. It was developed for bladder cancer patients with high-grade non-muscle-invasive disease who are being considered for treatment and patients with muscle-invasive disease who face the question of immediate cystectomy or systemic treatment in the neoadjuvant setting prior to cystectomy (NAC). Decipher Bladder reports the molecular subtype of the tumor specimen as Luminal or Non-Luminal (Luminal Infiltrated, Basal, Basal Claudin-Low or Neuroendocrine-like), with each subtype having distinct biological composition, clinical behavior and predicted benefit from NAC.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company that improves patient care by providing answers to clinical questions, informing diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The company's growing menu of diagnostic tests leverages advances in genomic science and technology, enabling patients to avoid risky, costly diagnostic procedures and quicken time to appropriate treatment. The company's tests in lung cancer, prostate cancer, breast cancer, thyroid cancer, bladder cancer, colon cancer, and idiopathic pulmonary fibrosis are available to patients and its renal cancer and lymphoma subtyping tests are in development, the latter as a companion diagnostic. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its genomic tests to patients worldwide. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, our statements related to our plans, objectives, expectations (financial and otherwise) or intentions with respect to the Decipher Bladder genomic classifier. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" "prospective" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. Examples of forward-looking statements include, among others, statements regarding Veracyte's belief that its Decipher Bladder molecular subtyping tool can assist healthcare providers in selecting patient treatment options. 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 with the SEC on February 22, 2021 and our subsequent quarterly reports on Form 10-Q. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, Veracyte specifically disclaims 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20211013005673/en/

Investor and Media Contact:
Tracy Morris
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.