



June 4, 2021

Veracyte Receives Final Medicare Coverage Policies for Decipher Bladder

First Molecular Subtyping Test to Gain Medicare Coverage to Inform Treatment for Individuals With Bladder Cancer

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 4, 2021-- [Veracyte, Inc.](#) (Nasdaq: VCYT) today announced that Medicare Administrative Contractors Palmetto GBA, WPS and CGS Administrators, LLC have finalized their coverage policies for Decipher Bladder, a genomic subtyping tool that helps physicians manage treatment decisions for patients with bladder cancer. These local coverage determinations (LCDs) make Decipher Bladder the first genomic test to be covered by Medicare for such patients. Developed through the Medicare MoIDX program, the policies will become effective July 18, 2021, and provide a framework for other participating MACs to follow.

Noridian Healthcare Solutions, another Medicare Administrative Contractor, is expected to similarly finalize its draft LCD, which will make Decipher Bladder a covered benefit for more than 62 million Medicare beneficiaries. In the United States, more than 80,000 individuals are diagnosed with bladder cancer annually, approximately 44,000 of which will have the non-metastatic, Stage I-IIIa disease indicated in these policies.

"Physicians treating patients with bladder cancer are faced with complex and potentially life-changing treatment decisions, including whether or not to prescribe neoadjuvant chemotherapy or proceed directly to radical cystectomy," said Tina Nova, Ph.D., Veracyte's general manager, urologic cancers. "Studies have demonstrated that knowledge of an individual's bladder-tumor molecular subtypes can help guide these decisions, over and above clinical features alone. The coverage decisions announced today will make it possible for physicians to access this critical genomic information."

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.

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 muscle-invasive disease who face the question of immediate cystectomy or systemic treatment in the neoadjuvant setting prior to cystectomy (NAC). The assay results are reported as one of five molecular subtypes (Luminal, Luminal-Infiltrated, Basal, Basal Claudin Low or Neuroendocrine-like), each of which has distinct biological composition, clinical behavior and predicted benefit from NAC.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global genomic 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 genomic 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 and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping and renal cancer tests are in development. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its 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. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "positioned," "designed" 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 among others, our ability to achieve and maintain Medicare coverage for our tests, including Decipher Bladder. Additional factors that may impact these forward-looking statements can be found in Item 1A --"Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 22, 2021 and in our Quarterly Report on Form 10-Q filed with the SEC on May 10, 2021. 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 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.

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