Veracyte Announces that New Data Show Immunoscore IC Assay May Predict Patients Likely to Benefit from Addition of Immunotherapy to Standard First-Line Therapy for Metastatic Colorectal Cancer

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Findings from Phase II AtezoTRIBE trial published online in The Lancet Oncology

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 31, 2022-- Veracyte, Inc. (Nasdaq: VCYT) announced today that new data published online in *The Lancet Oncology* suggest that the company's Immunoscore Immune Checkpoint (IC) assay may identify patients with metastatic colorectal cancer (mCRC) who are likely to benefit from the addition of immune checkpoint inhibitor (ICI) therapy to standard first-line treatment. The findings are from the randomized, controlled, phase II AtezoTRIBE trial, a multicenter Italian clinical study, sponsored by GONO Foundation.

The vast majority of mCRC tumors (approximately 95 percent) have a proficient DNA mismatch repair (pMMR) system and are microsatellite stable. These tumors have low immunogenicity and do not derive benefit from immune checkpoint inhibitors. Previous research suggests that the FOLFOXIRI and bevacizumab combination enhances immunogenicity in pMMR mCRC. In the current study, researchers found a modest benefit of the experimental treatment regimen in this subgroup.

"AtezoTRIBE is the first to show that the addition of the PD-L1 inhibitor atezolizumab to standard first-line treatment (FOLFOXIRI plus bevacizumab) improved progression-free survival in patients with previously untreated mCRC," said Chiara Cremolini, M.D., Ph.D., principal investigator of the trial and oncologist at the Pisa University Hospital in Italy.

Additionally, post-hoc statistical analyses designed to evaluate the association of immune-related biomarkers with treatment outcomes found a meaningful correlation between a "high" Immunoscore IC result and response to the experimental treatment regimen (p=0·003).

"To our knowledge, Immunoscore IC is the first biomarker with potential predictive value in selecting patients with pMMR metastatic colorectal cancer who are likely to benefit from the use of immune checkpoint inhibitors," said Carlotta Antoniotti, M.D., oncologist at the Pisa University Hospital and lead author of the new paper. "These findings must be confirmed in further prospective studies, but are encouraging as a means of addressing a significant unmet need."

"These findings are exciting, as they suggest new potential avenues for the use of the Immunoscore IC assay in identifying patients with metastatic colorectal cancer who may benefit from ICIs," said Corinne Danan, general manager for Veracyte's Biopharma business unit. "We believe the assay could help companies developing ICIs by enabling them to better identify appropriate patients for clinical trials."

About Immunoscore IC

Immunoscore IC is a novel assay designed to help predict a patient's response to immune checkpoint inhibitors. The assay measures the densities of PD-L1+ and CD8+ cells, as well as the proximity among these cells, on a single tissue section using imaging tools, and then produces a risk score based on a proprietary algorithm. The Immunoscore IC assay is available as a clinical research service for biopharmaceutical companies and is part of the Immunoscore family of assays. These assays measure the immune reaction in and around the tumor and help to determine drugs' mechanisms of action and their impact on the tumor microenvironment (TME). The Immunoscore Colon Cancer test is available clinically and analyzes T lymphocyte infiltration at the tumor site to help guide treatment decisions in localized colon cancer.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company that improves patient care by answering important clinical questions to inform diagnosis and treatment decisions. Our growing menu of advanced diagnostic tests help patients avoid risky, costly procedures and interventions, and reduce time to appropriate treatment. Our tests address eight of the 10 most prevalent cancers by incidence in the United States. In addition to making our tests available in the United States through our central laboratories, our exclusive license to a best-in-class diagnostics instrument positions us to deliver our tests to patients worldwide through laboratories that can perform them locally. 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 our clinical tests, assays, biopharma business opportunities and immuno-oncology offerings. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" "prospective," "potential" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. An example of a forward-looking statement includes, among others, that the Immunoscore IC assay is intended as a tool for predicting which patients may benefit from immune checkpoint inhibitors. 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 28, 2022, 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.

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Investors:

Shayla Gorman
Director, Investor Relations
investors@veracyte.com
619-393-1545

Media:
Tracy Morris
Vice President of Global Corporate Communications
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.