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New Data in Nature Medicine Suggest Pre-Treatment Tumor Microenvironment Can Impact Response for CAR T-Cell Therapy in Patients with Large B-Cell Lymphoma

Findings suggest Veracyte's immuno-oncology biomarkers could help predict response to therapy, improve patient outcomes and guide immunotherapy clinical trials

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 29, 2022-- Veracyte, Inc. (Nasdaq: VCYT) announced that new data published today in *Nature Medicine* provide the first evidence that the pre-treatment tumor microenvironment (TME) can impact response to chimeric-antigen-receptor (CAR) T-cell therapy among patients with large B-cell lymphoma (LBCL). The study findings demonstrated for the first time the prognostic and predictive capabilities of Veracyte's proprietary biomarkers among LBCL patients treated with CAR T-cell therapy.

"CAR T-cell therapies are changing the standard of care in cancer treatment, and their expanded use increases the need for tools to help identify the patients most likely to benefit from them. The prognostic and predictive roles of the TME have been described for solid tumors, but the importance of TME for CAR T-cell therapy outcomes, and particularly in LBCL, has not previously been established," said Jérôme Galon, Ph.D., research director at Inserm in France and senior vice president and scientific executive director at Veracyte, as well as lead author on the published paper. "This study is the first to demonstrate this important clinical connection, and also confirms Immunoscore CR and Immunosign as one of the first pre-treatment TME biomarkers to be associated with prolonged survival following CAR T-cell therapy."

This study aimed to identify biomarkers associated with CAR T-cell therapy outcomes in patients treated with Kite's axicabtagene ciloleucel (axi-cel), a first-in-class anti-CD19 CAR T-cell therapy. Study investigators conducted a retrospective analysis using Veracyte's Immunoscore Clinical Research (CR) and Immunosign 21 (IS21) assays, along with three custom panels (Immunoscore T-cell Exhaustion, TCE+ panels and Immunoscore Suppressive Cells panel) to compare pre-treatment TME patterns that were associated with improved response in Kite's ZUMA-1 study, the pivotal Phase 2 trial in adult patients with relapsed or refractory LBCL.

Results published today suggest that the pre-treatment tumor immune contexture was associated with, and potentially a major determinant of, clinical outcomes in ZUMA-1 patients. Improved clinical outcomes were more associated with high resolution pre-treatment immune contexture characterized by Immunoscore CR and Immunosign 21 rather than with general T-cell gene profiles and densities.

"These findings advance the understanding of the TME and its association with clinical responses to anti-CD19 CAR T-cell therapy in DLBCL and could therefore enhance clinical benefit and outcomes for patients," said Francesco Marincola, M.D., global head of Cell Therapy Research, Kite. "The availability of validated immuno-oncology biomarkers could support further clinical studies of these therapies, particularly in earlier lines of treatment, and help advance our ability to provide precision medicine for patients with hematologic malignancies."

In the study, researchers noted rapid and broad changes across post-treatment TME immune programs associated with improved response, with marked decrease in B-cell lineage gene expression in responders' TME.

Researchers also suggest that immune-based therapies with curative potential such as axi-cel should be considered in earlier lines of therapy where a larger percentage of patients have more favorable TME features and lower tumor burden, to potentially maximize clinical benefit.

"These findings suggest that our offerings can help provide key insights into the mechanism of action for immuno-therapies such as CAR T-cell treatment," said Corinne Danan, general manager for Veracyte's Biopharma business unit. "We believe our extensive capabilities and expertise in immuno-oncology position us well to serve biopharma companies that are developing cutting-edge treatments such as CAR T-cell therapies, immune checkpoint inhibitors and others."

About Veracyte's Immuno-Oncology Biopharma Offerings

Veracyte offers its biopharma partners unique, multi-omic capabilities, expertise and tools designed to optimize biomarkers, companion diagnostics and therapeutic clinical trials through robust analysis of patient oncology samples. These offerings include a comprehensive platform of immuno-oncology expertise and technologies focused on analyzing the tumor immune response. Assays currently available within this platform include Immunoscore, which measures patient immune response at the tumor site; Immunosign immune gene signature, which provides powerful pan-cancer immune gene signature analysis; and Brightplex multiplex spatial profiling, which provides quantitative immune phenotyping using digital pathology and image analysis software. For more information, please visit https://io.veracyte.com/.

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. 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 Veracyte immuno-oncology biomarkers can be used

to help predict which patients may benefit from CAR T-cell therapy including axi-cel; identify likelihood of relapse; and assist in identifying patients for clinical trials. 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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