Data Published in Annals of Oncology Reinforce Clinical Utility of Veracyte's Decipher Prostate Genomic Classifier for Informing Treatment of Men Experiencing Prostate Cancer Progression

June 3, 2022

First randomized, clinical study demonstrating prognostic value of Decipher Prostate test in postoperative salvage setting without hormone therapy

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 3, 2022-- Veracyte, Inc. (Nasdaq: VCYT) today announced the publication of data reinforcing the clinical utility of the Decipher Prostate genomic classifier for helping to guide the timing and intensity of therapy in men experiencing prostate cancer recurrence following radical prostatectomy (RP). The findings, from an ancillary study of the prospective open-label, multicenter, randomized phase 3 SAKK 09/10 trial conducted at 28 centers in Belgium, Germany, and Switzerland, appear i*n Annals of Oncology.*

It is estimated that more than 40 percent of men with intermediate- or high-risk prostate cancer may experience a biochemical disease recurrence after RP, which is characterized by rising levels of serum prostate-specific antigen (PSA). For men who experience a rising PSA, determining the optimal timing to initiate salvage radiotherapy (SRT) and whether to add androgen deprivation therapy (ADT) to SRT is challenging. This decision is important in part because the side effects of ADT when given concurrently with SRT are often difficult for patients to manage and are associated with long-term cardiovascular impact of hormone therapy.

"Each year in the United States, tens of thousands of men are diagnosed with biochemically recurrent prostate cancer, yet conventional clinical measures such as PSA and Gleason score are often insufficient to predict which of them will do well with SRT alone and who will need more intensive therapy to improve their oncologic outcomes," said Elai Davicioni, Ph.D., Veracyte's medical director for urology. "The data from this study suggest that the Decipher Prostate genomic classifier can help fill this gap by providing objective information to guide customized treatment planning in the postoperative setting."

Researchers in the Swiss Group for Clinical Cancer Research (SAKK) and collaborating cancer centers assessed the clinical outcomes and Decipher Prostate genomic risk for 226 prostate cancer patients from the SAKK 09/10 trial, which randomized patients to standard vs. dose-escalated SRT. This study involved men experiencing a rise in PSA following RP, all of whom received SRT without the addition of ADT. Patients in the Decipher Prostate analysis were followed for a median of 6.3 years.

Findings suggest that Decipher Prostate can identify the patients who are at highest risk of cancer progression following RP and would benefit from earlier, more intensive treatment. Patients with a high Decipher score were more than twice as likely than those with a lower Decipher score to experience biochemical and clinical progression, and to receive long-term salvage hormone therapy. Additionally, patients with high Decipher scores had markedly improved outcomes when treated with SRT when the PSA burden was still low as compared to late SRT, when PSA levels have already risen.

"These findings add meaningfully to the existing literature supporting the use of the Decipher Prostate RP test in postoperative decision-making. Decipher Prostate RP is the only genomic test backed by evidence from randomized Phase 3 trials and we look forward to our continued collaboration with the SAKK team, with studies aimed at further elucidating the subset of men that benefit most from dose-escalation," said Dr. Davicioni.

About Decipher Prostate

Decipher Prostate is a 22-gene, microarray-based genomic test intended to help inform treatment decisions for men with localized prostate cancer at initial diagnosis (Decipher Prostate Biopsy) and after surgical removal of the prostate (Decipher Prostate RP). The test reports the Decipher Score, which prognosticates a patient's risk of metastasis within five years and provides risk estimates of prostate cancer-specific outcomes. Decipher Prostate can help guide physicians to better select the appropriate therapy for a specific patient, which in turn can result in improved patient outcomes. Decipher Prostate is available as part of Veracyte's CLIA-validated laboratory developed test (LDT) service. This test has not been cleared or approved by the FDA.

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 the Decipher Prostate. 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. An example of a forward-looking statement includes, among others, that the Decipher Prostate genomic classifier can help physicians guide prostate cancer treatment. 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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