April 29, 2023

Findings From Two Large-Scale, Real-World Data Sets Reinforce Clinical Utility of Veracyte's Decipher Prostate Genomic Classifier

Data from studies encompassing over 100,000 prostate cancer patients presented at American Urology Association (AUA) 2023 Annual Meeting

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 29, 2023-- Veracyte, Inc. (Nasdaq: VCYT) announced that new data presented at the American Urological Association (AUA) 2023 Annual Meeting validate the real-world performance and clinical utility of the company's Decipher Prostate Genomic Classifier. The findings are from two separate, large-scale studies evaluating the Decipher Prostate test among a total of more than 100,000 individuals with prostate cancer and reinforce its role as a new standard of care to help inform treatment decisions for these patients.

"The prognostic performance and utility of the Decipher Prostate test have been established previously in the context of more than 70 peer-reviewed publications," said Elai Davicioni, Ph.D., Veracyte's medical director for Urology. "These new, large-scale studies demonstrate that the Decipher Prostate test's performance and utility are being confirmed in the real world and should give physicians even further confidence in the test's results and clinical value."

The 22-gene Decipher Prostate Genomic Classifier provides a score ranging from 0 to 1, categorized as low (<0.45), intermediate (0.45-0.60) and high risk (>0.60) of metastasis. It is the most validated prognostic biomarker for risk stratification among patients with prostate cancer to help determine who may benefit from treatment intensification.

In the first study presented at AUA2023 (#MP44-17), researchers used data from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) database, the most commonly used cancer database in the United States, to examine treatment with conservative management (i.e., active surveillance) among patients with favorable-risk disease who were tested with the Decipher Prostate classifier. Specifically, the researchers examined the relationship between the Decipher test results, receipt of treatment and adverse pathology (AP) at the time of radical prostatectomy (RP) - a surrogate for poor outcomes in this otherwise low-risk population.

Researchers linked data from 2,744 patients in the SEER registry who were tested with the Decipher Prostate test between 2016 and 2020. They then quantified the association of these patients' Decipher Prostate test scores with receipt of surgery, upgrading, upstaging and adverse pathology at RP, and compared these associations to those of tumor volume, PSA, patient age and Gleason score at diagnosis.

Results show that Decipher Prostate testing – regardless of individual patients' test scores – was independently associated with a two-fold increase in conservative management utilization among those with favorable-risk disease (OR 2.1, 95% CI 1.9-2.5, p<0.001). Additionally, higher Decipher Prostate scores were associated with RP, upgrading, upstaging and AP, whereas greater tumor volume was only significantly associated with receipt of RP.

"Importantly, this study shows that while both high Decipher Prostate test scores and higher tumor volume are associated with a higher likelihood that patients will undergo radical prostatectomy, only higher Decipher scores are associated with an increased rate of adverse pathology at the time of RP," said Jim C. Hu, MD, MPH, professor of Urology at Weill Cornell Medicine, and the principal investigator on the study. "This suggests that Decipher Prostate testing at the time of biopsy may improve risk stratification for prostate cancer patients with favorable-risk disease independent of tumor volume. Additionally, our findings suggest that patients with lower Decipher scores who have higher volume tumors may be suitable candidates for conservative management."

Findings from a second, real-world study were shared in two posters at AUA2023. The first poster (#MP17-09) describes the first, national-scale linkage of transcriptomic and longitudinal data in prostate cancer. Researchers confirmed that the linkage, which includes data from 92,976 patients tested with the Decipher Prostate classifier, yields data that are highly accurate for identifying key clinical junctures including diagnosis, treatment and early clinical outcomes (biochemical recurrence and prostate cancer metastases).

The second poster (#MP17-02) highlights results from a retrospective cohort study that utilized the above linkage database to evaluate the association between Decipher Prostate classifier results and prostate cancer outcomes in real-world clinical practice. Specifically, researchers evaluated the associations between Decipher Prostate test results and biochemical recurrence (BCR), along with metastasis after RP (n=39,015) and prostate biopsy (n=53,871).

The study found that Decipher Prostate test results in contemporary practice were independently associated with risk of metastasis in patients at diagnosis (hazard ratio [HR] 1.22 per 0.1-unit increase) and with both risk of BCR (HR 1.14 per 0.1-unit increase) and metastasis (HR 1.18 per 0.1-unit increase) in the RP-treated patients.

"We believe the findings from this large-scale, real-world study add meaningfully to the substantial body of data demonstrating the clinical utility of the Decipher Prostate test," said Michael Leapman, MD, MHS, clinical program leader for the Prostate & Urologic Cancers Program at Yale Cancer Center, and the principal investigator on the study. "From a clinician's perspective, these results are significant because they demonstrate the prognostic value of a genomic test as used on real patients receiving prostate cancer care in the contemporary era."

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company whose vision is to transform cancer care for patients all over the world. We empower clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Our high-performing tests enable clinicians to make more confident diagnostic, prognostic, and treatment decisions for some of the most challenging diseases such as thyroid, prostate, breast, bladder and lung cancers, as well as interstitial lung diseases. We help patients avoid unnecessary procedures and speed time to diagnosis and appropriate treatment. In addition to making our tests available in the U.S. through our central

laboratories, we also aim to deliver our tests to patients worldwide through a distributed model to 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 in and outside of the United States. 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. Examples of forward-looking statements include, among others, that the Decipher Prostate Genomic Classifier, at the time of biopsy, may improve risk stratification for prostate cancer patients with favorable-risk disease independent of tumor volume and that patients with lower Decipher scores who have higher volume tumors may be suitable candidates for conservative management. 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 on February 22, 2023, and our Quarterly Report on Form 10-Q filed for the three months ended December 31, 2022. Copies of these documents, when available, may be found in the Investors section of our website at https://investor.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim 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.

Veracyte, the Veracyte logo and Decipher are registered trademarks of Veracyte, Inc. and its subsidiaries in the U.S. and selected countries. nCounter is the registered trademark of NanoString Technologies used by Veracyte under license.

Veracyte delivers the Decipher Prostate Genomic Classifier from its CLIA laboratories. Those tests are not CE-IVD marked and have not been cleared or approved by the FDA; their performance characteristics were determined by Veracyte and they might be considered for Research Use Only in some markets. Please contact Veracyte for confirmation.

View source version on businesswire.com: https://www.businesswire.com/news/home/20230429005033/en/

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.