May 26, 2021

Veracyte Announces New Data Demonstrating Afirma Xpression Atlas Identifies Clinically Relevant Gene Fusions in Thyroid Cancer FNA Samples

Study findings to be presented June 4 at ASCO Annual Meeting

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 26, 2021-- Veracyte, Inc., (Nasdaq: VCYT) announced today new data that show the company's Afirma Xpression Atlas (XA) can identify clinically relevant gene fusions in thyroid nodule samples collected via fine needle aspiration (FNA). The findings, which will be presented June 4 at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, support use of the whole transcriptome RNA-sequencing test to detect gene fusions that may guide the use of targeted treatments for thyroid cancer.

"The increasing availability of targeted therapies for thyroid cancer, including tyrosine kinase inhibitors, means physicians must have tools that reliably identify the patients who may benefit from these therapies," said Lori J. Wirth, M.D., medical director of the Center for Head and Neck Cancers, Mass General Cancer Center, who will present the data. "Using the Afirma XA test, we were able to identify and report the prevalence of clinically relevant gene variants and fusions in real-world thyroid nodule samples."

The American Cancer Society predicts that more than 44,000 individuals will be diagnosed with thyroid cancer in the United States this year. Pathologists use the Bethesda system to classify thyroid nodules into several categories – from benign to malignant – using FNA samples. The Afirma XA uses whole transcriptome RNA sequencing to identify 905 DNA variants and 235 RNA fusions in 593 genes on FNAs taken from thyroid nodules. Increasing numbers of these gene fusions can be targeted by small-molecule therapies.

In the study to be presented at ASCO (Abstract 6803), researchers analyzed data from 50,644 thyroid FNA samples submitted to Veracyte's CLIA laboratory to determine the prevalence of selected receptor tyrosine kinase (RTK) fusions of *ALK*, *BRAF, NTRK1/3 or RET* fusions. The Afirma Genomic Sequencing Classifier (GSC) had been used to classify samples as benign or suspicious following an indeterminate result by cytopathology (Bethesda III-IV). Researchers performed the Afirma XA on samples that were deemed suspicious by the GSC or that were likely or confirmed cancerous by cytopathology (Bethesda V/VI).

More than 32,000 samples were classified as benign with the Afirma GSC and no RTK fusions were identified. Of the 16,594 samples classified as suspicious by the Afirma GSC, 3% harbored RTK fusions. In the nearly 1,700 samples classified as either suspicious for malignancy or malignant, 8% were found to have RTK fusions. The most common fusion was ETV6/NTRK3, while BRAF fusions had the most diversity with 80 different gene partners.

"These findings suggest that by using the Afirma GSC and XA tests, physicians can confidently classify individual patients' thyroid nodules and, for nodules that are malignant, determine whether treatment with a targeted therapy is appropriate," said Richard T. Kloos, M.D., Veracyte's executive medical director. "We look forward to future analyses of how Afirma XA test results impact initial treatment and patient outcomes."

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 leverage 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 with respect to the Afirma Genomic Sequencing Classifier (GSC) and the Afirma Xpression Atlas (XA) test. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. Examples of forward-looking statements include, among others, statements regarding Veracyte's belief that its Afirma XA can identify clinically relevant gene variants and thereby assist health care providers in selecting thyroid cancer treatment options. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to: Veracyte's ability to achieve and maintain Medicare coverage for its tests; the benefits of Veracyte's tests and the applicability of clinical results to actual outcomes. 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 22, 2021 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. The risks and uncertainties may be amplified by the COVID-19 pandemic, which has caused significant economic uncertainty. The extent to which the COVID-19 pandemic impacts Veracyte's businesses, operations, and financial results, including the duration and magnitude of such effects, will depend on numerous factors, which are unpredictable, including, but not limited to, the duration and spread of the outbreak, its severity, the actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume. 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.

nCounter is the registered trademark of NanoString Technologies, Inc. in the United States and other countries and used by Veracyte under license.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210526005406/en/

Investor and Media Contact:
Tracy Morris
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.