April 1, 2020

Veracyte Announces Novel Gene Fusion Detection with the Afirma Xpression Atlas, Which May Inform Targeted Treatment Decisions for Thyroid Cancer Patients

Company launches expanded content to detect novel NTRK, ALK, RET and BRAF fusions at time of diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 1, 2020-- Veracyte, Inc. (Nasdaq: VCYT) today announced results of a study that identified over 100 novel or rare *NTRK, ALK, RET* and *BRAF* fusions in fine needle aspiration (FNA) samples of patients undergoing evaluation for thyroid cancer. These gene fusions – 70 of which are previously unreported – may potentially be targeted with specific kinase inhibitor drugs that are currently available or in development for use in thyroid cancer patients. Veracyte also announced that it has launched an expanded version of its Afirma® Xpression Atlas (XA) test, which uses RNA sequencing to detect gene alterations – including these novel or rare fusions – at the time of diagnosis.

The new data are featured in an abstract that was accepted for an oral presentation this week at ENDO 2020*, the annual meeting of The Endocrine Society. The study was one of two Afirma XA-related abstracts accepted for the meeting.

For the new study, researchers performed RNA whole-transcriptome sequencing on over 37,000 thyroid nodule FNA samples whose cytopathology results were either indeterminate (Bethesda III/IV) or suspicious for cancer (Bethesda V/VI). They found 104 novel or rare gene fusions – 7 *NTRK1/3*, 8 *ALK*, 17 *RET* and 72 *BRAF* – none of which were previously reported for thyroid cancer in The Cancer Genome Atlas (TCGA) program, a United States government catalogue of gene alterations associated with cancer. The authors subsequently examined over 50,000 FNA samples that had undergone testing with Veracyte's Afirma Genomic Sequencing Classifier (GSC) and found that none of the novel or rare gene fusions were detected among those deemed benign. *NTRK, ALK, RET* and *BRAF* fusions, including those in the new study, were identified in 3.2 percent of the 16,594 Bethesda III/IV samples that were deemed suspicious for cancer by the Afirma GSC and in 8.0 percent of the 1,692 Bethesda V/VI samples.

"Identification of receptor tyrosine kinase fusions is important because they are potential targets for small molecule inhibitors that are now FDA-approved or in clinical trials to treat advanced thyroid cancers," said Lori J. Wirth, M.D., medical director of the Center for Head and Neck Cancers at Massachusetts General Hospital and lead author of the study. "By examining a large cohort of patients with RNA whole-transcriptome sequencing, we identified potentially actionable RTK fusions in thyroid nodules beyond those described in TCGA, which may have an impact on treatment decisions for many patients."

Veracyte also announced the introduction of its expanded Afirma XA, which provides physicians with additional gene alteration content – including the novel or rare *NTRK, ALK, RET* and *BRAF* fusions from the new study – to further inform surgery and treatment decisions for patients with suspected or confirmed thyroid cancer. The Afirma XA utilizes RNA sequencing on the same FNA sample used for Afirma GSC testing. Compared to the original gene alteration panel, the expanded Afirma XA now reports 905 DNA variants (versus 761) and 235 RNA fusion partners (versus 130) in 593 genes (versus 511).

"By including additional gene fusion data that can potentially be targeted with new therapies, the expanded Afirma XA provides physicians with even more powerful information with which to guide surgery and treatment decisions in their patients with thyroid cancer," said Richard T. Kloos, M.D., senior medical director of endocrinology at Veracyte. "Importantly, the Afirma XA provides this information pre-operatively through a minimally invasive FNA sample."

In the second Afirma XA-focused abstract accepted for ENDO 2020 – as a poster presentation – researchers reported on the positive predictive value of *TP53* gene variants among thyroid nodules deemed suspicious for cancer by the Afirma GSC following indeterminate cytopathology results.

About Afirma

The Afirma Genomic Sequencing Classifier (GSC) and Xpression Atlas provide physicians with a comprehensive solution for thyroid nodule diagnosis. The Afirma GSC was developed with RNA whole-transcriptome sequencing and machine learning and helps identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to help patients avoid unnecessary diagnostic thyroid surgery. For those with suspected thyroid cancer, the Afirma Xpression Atlas provides physicians with genomic alteration content from the same fine needle aspiration samples that are used in Afirma GSC testing and may help physicians decide with greater confidence on the surgical or therapeutic pathway for their patients.

About Veracyte

Veracyte (Nasdaq: VCYT) is a leading genomic diagnostics company that improves patient care by providing answers to clinical questions that inform diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. The company's core products are uniquely developed with RNA whole-transcriptome sequencing and machine learning to deliver results that give patients and physicians a clear path forward. Since its founding in 2008, Veracyte has commercialized seven genomic tests and is transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis. In December 2019, Veracyte acquired the exclusive global diagnostic rights to the nCounter platform from NanoString Technologies, Inc., through which it plans to make its genomic tests available to physicians and their patients worldwide. These include commercial and in-development tests in breast cancer and lymphoma, respectively, which Veracyte also acquired through the transaction. 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" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will" and similar references to future

periods. Examples of forward-looking statements include, among others, statements regarding Veracyte's expectations regarding the ability of the Afirma Xpression Atlas to detect novel or rare fusions in the evaluation of thyroid cancer, the expected impacts of the acquisition from NanoString on Veracyte, including its ability to expand its platform globally, its ability to increase the efficiency of its advanced genomic testing, and its plans to transfer its current and pipeline genomic tests onto the nCounter system; Veracyte's ability to advance the development and commercialization of novel diagnostic tests under the collaboration with Johnson & Johnson; the ability of Veracyte to achieve the expected benefits from the Acerta collaboration; and its ability to potentially inform diagnosis and treatment decisions in new oncology indications. Forward-looking statements are neither historical facts nor assurances of future performance, but are based only on our current beliefs, expectations and assumptions. 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 our tests and the applicability of clinical results to actual outcomes; the laws and regulations applicable to Veracyte's business, including potential regulation by the Food and Drug Administration or other regulatory bodies; Veracyte's ability to successfully achieve and maintain adoption of and reimbursement for its products; the amount by which use of Veracyte's products are able to reduce invasive procedures and misdiagnosis, and reduce healthcare costs; the occurrence and outcomes of clinical studies; and other risks set forth in Veracyte's filings with the Securities and Exchange Commission, including the risks set forth in its annual report on Form 10-K for the year ended December 31, 2019. These forward-looking statements speak only as of the date hereof and 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.

*ENDO 2020 has been canceled due to the COVID-19 pandemic.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200401005127/en/

Investor Contact:
Keith Kennedy
Chief Operating Officer and Chief Financial Officer
650-243-6357
keith@veracyte.com

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

Source: Veracyte, Inc.