Veracyte Announces Publication of Clinical and Analytical Validation Data for Afirma Xpression Atlas

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RNA whole-transcriptome sequencing test informs thyroid cancer treatment decisions at time of diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 11, 2019-- Veracyte, Inc. (Nasdaq: VCYT) today announced the publication of new data demonstrating the clinical and analytical validity of its Afirma® Xpression Atlas (XA) genomic test, which is used to help guide surgery and treatment decisions for patients with likely or confirmed thyroid cancer. The new findings appear online in the journal *Frontiers in Endocrinology*.

The Afirma XA uses RNA whole-transcriptome sequencing to detect expressed DNA variants and RNA fusion partners in over 500 genes that are associated with thyroid cancer. The test is performed on fine needle aspiration (FNA) samples of thyroid nodules deemed suspicious for cancer by Veracyte's Afirma Genomic Sequencing Classifier (GSC), as well as those that are suspicious for or have been diagnosed as cancer based on cytopathology. Importantly, the Afirma XA is performed on the same FNA sample as the Afirma GSC, obviating the need for patients to undergo an additional FNA procedure to obtain this genomic information about their thyroid.

To evaluate the Afirma XA's clinical validity, researchers compared the test's ability to identify genomic variants in an FNA sample's transcriptome to currently accepted methods of targeted DNA and RNA sequencing. Using 943 blinded FNA samples, they found the Afirma XA had high positive predictive agreement (PPA) with targeted DNA sequencing (88 percent) and targeted RNA sequencing (89 percent). Similarly, using 695 blinded FNA samples to look for RNA fusions, the Afirma XA had an 82 percent PPA with targeted RNA sequencing. Conversely, 95 percent or more of variants and fusions identified by Veracyte's RNA whole-transcriptome sequencing test were also identified by the reference method.

"Our findings suggest that the Afirma XA is sensitive and accurate in identifying gene alterations that are associated with thyroid cancer and confirm that the test can do this using one patient sample for all molecular testing," said Trevor E. Angell, assistant professor of clinical medicine at the Keck School of Medicine of USC and lead author of the new paper. "The extensive genomic-alteration information provided by the Afirma test can help physicians tailor initial treatment for patients with likely or confirmed cancer and also provides information about the potential benefits of targeted therapies for those cancers that don't respond to standard treatment."

The researchers also investigated the reproducibility of the Afirma XA across laboratories and reagent lots. Using 69 variant-positive FNA samples, they found that the Afirma XA showed high accuracy between two different labs with different personnel for detecting variants (90 percent) and fusions (94 percent).

"The use of pre-operative molecular testing with minimally invasive FNA samples is expanding beyond cytologically indeterminate thyroid nodules to include those nodules with clear malignancy. Our findings demonstrate that physicians can be confident in the Afirma XA's results at the time of diagnosis, which help guide surgery and treatment decisions," said Richard T. Kloos, M.D., medical director of endocrinology for Veracyte and an author of the new study.

About Afirma Genomic Testing

The Afirma GSC and Xpression Atlas provide physicians with a comprehensive solution for a complex landscape in thyroid nodule diagnosis and individualization of care. Veracyte developed the Afirma GSC with RNA whole-transcriptome sequencing and machine learning. The test helps identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to help patients avoid unnecessary diagnostic thyroid surgery. The Afirma XA provides physicians with genomic alteration content from the same fine needle aspiration samples that are used in Afirma GSC testing and may help physicians make decisions about the surgical or therapeutic pathway for their patients with greater confidence. The Afirma XA includes 761 variants and 130 fusion partners in over 500 genes that are associated with thyroid cancer.

About Thyroid Cancer

The American Cancer Society estimates that 54,070 people in the United States will be diagnosed with thyroid cancer in 2019. Each year in the United States approximately 525,000 patients undergo FNA biopsies to evaluate thyroid nodules for cancer. Up to 30 percent of these patients receive indeterminate results – meaning they are not clearly benign or malignant – and, historically, most were directed to diagnostic surgery even though 70 percent to 80 percent of the time the nodules ultimately proved to be benign. For patients diagnosed with thyroid cancer, multiple precision medicine therapies are now available or in development to treat the cancer based on its genomic profile.

About Veracyte

Veracyte (Nasdaq: VCYT) is a leading genomic diagnostics company that improves patient care by providing trustworthy and actionable answers to challenging clinical questions. The company's products uniquely combine advanced genomic technology, clinical science and machine learning to provide answers that give patients and physicians a clear path forward, informing both diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. 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. 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, the ability of Veracyte's Afirma Xpression Atlas to help characterize medullary thyroid cancer and to guide surgery and treatment decisions, and the ability of FNA samples to analyze suspicious thyroid nodules. 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: our ability to achieve milestones under the collaboration agreement with Johnson & Johnson; our ability to achieve and

maintain Medicare coverage for our tests; the benefits of our tests and the applicability of clinical results to actual outcomes; the laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our ability to successfully achieve and maintain adoption of and reimbursement for our products; the amount by which use of our 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 our filings with the Securities and Exchange Commission, including the risks set forth in our quarterly report on Form 10-Q for the quarter ended June 30, 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, except as required by law.

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