Veracyte Announces New Publication of Data Demonstrating Real-World Performance of the Afirma GSC in Thyroid Cancer Diagnosis

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 10, 2019-- Veracyte, Inc. (Nasdaq: VCYT) announced today that findings from a new real-world study show that the company's Afirma ® Genomic Sequencing Classifier (GSC) helps to identify significantly more benign thyroid nodules and further reduce unnecessary surgeries in thyroid cancer diagnosis, as compared to the original Afirma test. Findings from the clinical utility study, conducted by researchers at The Ohio State University, appear online in the journal *Thyroid* and add to the growing body of independent evidence demonstrating the performance of the next-generation genomic test.

In the study, researchers evaluated records for all patients whose thyroid nodules were indeterminate for cancer based on cytopathology and who subsequently underwent molecular testing with the Afirma GSC or the original Afirma Gene Expression Classifier (GEC) between February 2011 and December 2018. Based on a cohort of 164 Afirma GSC-tested nodules and 343 Afirma GEC-tested nodules, they found that the next-generation test identified 58 percent more nodules as benign (76.2 percent vs. 48.1 percent) and that the rate of surgery among indeterminate thyroid nodules decreased by 66.4 percent (from 52.5 percent with the Afirma GEC to 17.6 percent with the Afirma GSC). The "benign call" rate among Hürthle cells – a common but difficult-to-diagnose thyroid nodule subtype – was also significantly higher using the Afirma GSC (88.8 percent vs. 25.7 percent).

"Our findings show that use of the Afirma GSC has enabled us to identify many more patients as benign when their thyroid nodules were indeterminate compared to the original test and, as a result, to help significantly reduce unnecessary thyroid surgeries among these patients," said Jennifer A. Sipos, M.D., endocrinologist and professor at The Ohio State University and an author of the new study. "The next-generation test's results were particularly striking for patients with Hürthle cells who previously had little other choice than to undergo diagnostic surgery, which carries risks and is costly."

The new study marks the third recent independent publication by a major medical center demonstrating that its use of the Afirma GSC helped to significantly reduce surgeries in thyroid cancer diagnosis.

"These findings clearly demonstrate that, as compared to our original test, our Afirma GSC is delivering even more value to patients who are undergoing evaluation for thyroid cancer, as well as to physicians and the healthcare system," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "This study further underscores the power of our next-generation RNA whole-transcriptome sequencing and machine learning platform to answer important clinical questions that help guide a patient's medical journey."

About Afirma

The Afirma Genomic Sequencing Classifier (GSC) and Xpression Atlas provide physicians with a comprehensive solution for a complex landscape in thyroid nodule diagnosis. The Afirma GSC was developed with RNA whole-transcriptome sequencing and machine learning, and commercially introduced in 2017. 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. Clinical validation data published in *JAMA Surgery* show that the next-generation classifier maintains the original Afirma test's high sensitivity (91 percent), while identifying 30 percent more benign nodules (68 percent specificity) among those deemed indeterminate by cytopathology. 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. The Afirma Xpression Atlas includes 761 DNA variants and 130 RNA fusion partners in over 500 genes that are associated with thyroid cancer.

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 physicians and patients 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 five genomic tests, which are 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. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to statements about: the ability of Veracyte's Afirma GSC to improve upon the original Afirma GEC and to identify Hürthle cells, the ability of Veracyte's Afirma Xpression Atlas to help characterize medullary thyroid cancer, 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; the size of our addressable market; 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 March 31, 2018. 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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