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Veracyte Announces That Data From Multiple Studies Demonstrate “Real-World” Value of Afirma Genomic Sequencing Classifier in Thyroid Cancer Diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 19, 2018-- Veracyte, Inc. (Nasdaq: VCYT) announced that early user-experience data from three independent studies demonstrate that the next-generation Afirma Genomic Sequencing Classifier (GSC) significantly increases the number of patients who can avoid unnecessary surgery in thyroid cancer diagnosis, compared to the original, market-leading Afirma Gene Expression Classifier. The findings were presented today during poster sessions at the AACE 27th Annual Scientific & Clinical Congress, being held May 16-20 in Boston.

In each study, researchers found that the Afirma GSC identified significantly more benign thyroid nodules among those deemed indeterminate – not clearly benign or malignant – by cytopathology review, compared to the first-generation test. Each institution began using the next-generation test shortly after it was introduced in July 2017 and, prior to that, had used the original Afirma test for several years.

Researchers from The Ohio State University found that among 47 indeterminate cases that underwent Afirma GSC testing, the next-generation test identified nearly three fourths (72.3 percent) of the patients as benign. This was significantly higher than the nearly half (48.4 percent) that were identified as benign by GEC testing from 2011 thorough mid-2017.

“Based on its previously demonstrated high negative predictive value, the Afirma GSC gives physicians and patients significant confidence in deciding to avoid surgery when the genomic test result is benign,” said Jennifer A. Sipos, M.D., endocrinologist and professor at The Ohio State University. “Our new findings show that the next-generation test identifies significantly more patients as benign, which means we can confidently keep even more patients out of the operating room. This is rewarding because, as a physician, I don’t want to send patients to surgery if they don’t need it.”

In a separate presentation, R. Mack Harrell, M.D., of the Memorial Center for Integrative Endocrine Surgery in Boca Raton, Fla., showed that at his institution the Afirma GSC identified approximately 51 percent more indeterminate nodules as benign, compared to the first-generation Afirma test. Among the particularly challenging sub-set of thyroid nodules known as Hürthle-cell dominant, use of the next-generation test resulted in a 49 percent increase in the percentage of nodules classified as benign.

“Our findings were quite striking, particularly the Afirma GSC’s increased yield of benign results in cases that were Hürthle-cell dominant,” said Dr. Harrell. “Using the next-generation test, we learned that we’ve sent 19 percent fewer patients to surgery, including significantly fewer patients with Hürthle-cell dominant nodules.”

Researchers from Lankenau Medical Center also shared findings that similarly showed an improvement in the rate of benign nodules found at their institution using the Afirma GSC.

“Our original Afirma test has already transformed thyroid cancer diagnosis, helping more than an estimated 40,000 patients avoid unnecessary surgery,” said Bonnie Anderson, Veracyte’s chairman and chief executive officer. “These new findings confirm that, by combining powerful RNA sequencing and machine learning advances, the Afirma Genomic Sequencing Classifier can identify even more patients with benign thyroid nodules and help to further reduce the major problem of overtreatment in thyroid cancer.”

About Afirma

Veracyte’s Afirma solution provides a comprehensive solution for physicians evaluating patients with potentially cancerous thyroid nodules. The Afirma Genomic Sequencing Classifier combines RNA sequencing data with machine learning to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to avoid unnecessary surgery and preserve the thyroid. Since the commercial introduction of Afirma in 2011, Veracyte has performed over 100,000 genomic tests, and estimates it has saved more than 40,000 patients from unnecessary thyroid surgery and removed an estimated $800 million in surgery costs from the healthcare system. The Afirma classifier is proven in over 20 published clinical studies, is included in most leading clinical guidelines and is covered as medically necessary by Medicare and all major U.S. health plans. The company’s Afirma Xpression Atlas platform, introduced in May 2018, provides extensive genomic data that may inform surgery strategy and treatment options for patients with thyroid nodules that are suspicious for cancer. The RNA sequencing-based platform measures 761 DNA variants and 130 RNA fusions in over 500 genes shown to be associated with thyroid cancer on thyroid nodule fine needle aspiration samples.

About Veracyte

Veracyte, Inc. (Nasdaq: VCYT) is a leading genomic diagnostics company that is providing trustworthy and actionable answers that fundamentally improve patient care when current diagnostic tests are uncertain. The company's products uniquely combine genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward without risky, costly surgery that is often unnecessary. Since its founding in 2008, Veracyte has commercialized three genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis and collectively target a $2 billion market opportunity. 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, our belief that our genomic tests will transform the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis; statements about our expectations for our genomic tests following the results of recent studies; statements regarding our Afirma Xpression Atlas platform, which we plan to introduce soon; and Afirma’s ability to significantly improve patient care

and reduce healthcare costs. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Forward-looking statements involve risks and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the benefits of our tests, 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 sell our Afirma tests and successfully transition to our next-generation Afirma GSC; 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 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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