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Veracyte Announces New Data Suggesting Afirma GSC's Ability to Help Significantly More Patients Avoid Unnecessary Thyroid Surgery

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 19, 2018-- Veracyte, Inc. (Nasdaq: VCYT) today announced that new data presented at ENDO 2018, the annual meeting of the Endocrine Society, suggest that the Afirma Genomic Sequencing Classifier (GSC) can help significantly more patients avoid unnecessary surgery in thyroid cancer diagnosis, compared to the original Afirma test. The findings were presented in a poster session during the conference, being held March 17-20 in Chicago.

"Our study is the first to assess how the Afirma GSC performs in real-world clinical practice," said Michael H. Shanik, M.D., an endocrinologist with Endocrine Associates of Long Island, who presented the new findings. "We found that the enhanced genomic test identified nearly two thirds of patients as benign – which is even more than was reported in our clinical validation study and reflects a significant increase compared to the original Afirma test."

In the new study of 5,478 consecutive samples evaluated with the Afirma GSC following indeterminate cytopathology results, researchers found that the Afirma GSC identified 64 percent as benign and 36 percent as suspicious for cancer. In comparison, they found that the original Afirma test identified 44 percent of patients as benign following indeterminate cytopathology. Because of the Afirma classifier's previously demonstrated high negative predictive value (95 percent), patients with benign genomic testing results are typically monitored with imaging in lieu of undergoing diagnostic surgery.

"Our original Afirma test has already transformed thyroid cancer diagnosis, where we estimate it has helped tens of thousands of patients avoid unnecessary surgery and saved significant healthcare costs," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "The Afirma GSC builds on that success, combining deep RNA sequencing and machine learning to provide a more granular genomic assessment of thyroid nodules. As a result, the Afirma GSC can better distinguish between even challenging thyroid biologies, such as Hurthle cells, and keep even more patients safely out of the operating room."

About Afirma

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 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 included in most leading clinical guidelines and is covered as medically necessary by Medicare and all of the major U.S. health plans. The company plans to introduce the Afirma Xpression Atlas platform soon, which will use RNA sequencing to extract extensive genomic data – including gene expression, variants and fusions – from thyroid cytology 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 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 annual report on Form 10-K for the year ended December 31, 2017, and our other filings with the SEC, including our quarterly reports on Form 10-Q and current reports on Form 8-K. 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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