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Veracyte Announces Publication of New Study Characterizing Gene Alterations in Thyroid Cancer

Data support use of Afirma Xpression Atlas to inform surgery and treatment decisions at time of diagnosis

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 3, 2019-- Veracyte, Inc. (Nasdaq: VCYT) today announced the publication of new data that further define the genomic landscape around thyroid cancer. The study findings help characterize the role of specific gene alterations known as variants and fusions in predicting thyroid cancer and also reinforce the potential for Veracyte's Afirma ® Xpression Atlas (XA) genomic test to help guide personalized surgery and treatment decisions for patients with suspected or confirmed thyroid cancer. The new study appears online in the journal *Thyroid*.

For the new analysis, researchers evaluated data from 61 published studies involving 4,648 thyroid nodule samples to determine the frequency of specific variants and fusions and the likelihood of cancer when they are detected in preoperative patient samples. The study focused on thyroid nodule samples that were indeterminate – not clearly benign or malignant – following traditional diagnostic testing.

Key findings include:

- More than one quarter (26%) of the total thyroid nodules were positive for at least one gene alteration, and of those, 94% were DNA sequence variants and 6% were RNA fusions;
- Only five specifically reported gene alterations appeared in 10 or more nodules in the collective cohort and less than one percent of the total thyroid nodules had more than one variant or fusion;
- The positive predictive value (PPV) – or likelihood that a variant or fusion was found in thyroid nodules that ultimately proved cancerous – varied significantly among the five most prevalent gene alterations [*BRAFV600E* (98%), *PAX8/PPARG* (55%), *HRASQ61R* (45%), *BRAFK601E* (42%) and *NRASQ61R* (38%)]; and
- The cumulative PPV for these five gene alterations was 77%; the PPV decreased to 47% when *BRAFV600E* was excluded.

"A key takeaway from our analysis is that gene variants and fusions carry different levels of cancer risk and should therefore be considered individually in thyroid cancer diagnosis and treatment decision-making. This means that use of multiple-gene panels to rule in or rule out cancer may be too blunt a tool in the emerging era of precision medicine," said Whitney S. Goldner, M.D., of the University of Nebraska Medical Center and lead author on the new paper. "We also found inconsistencies in the details reported about specific gene variants and fusions in the studies we evaluated. As researchers increasingly focus on the role of individual gene alterations in thyroid cancer, standardized reporting of this information will be very important."

"In the near future, knowing cancer's molecular profile will be at least as important as knowing its histological subtype. Our study findings reinforce the value of the Afirma XA in identifying the presence, as well as clinical relevance, of specific gene alterations found in preoperative thyroid nodules," said Richard T. Kloos, M.D., medical director of endocrinology for Veracyte and an author of the new study. "This personalized information helps guide surgery and treatment decisions and is derived from the same minimally invasive sample that the Afirma GSC uses in thyroid cancer diagnosis, meaning the patient can avoid additional fine needle aspiration procedures."

The study findings support the use of the Afirma XA, an RNA whole-transcriptome sequencing-based test that detects expressed DNA variants and RNA fusion partners in over 500 genes that are associated with thyroid cancer. DNA variants are alterations in the most common DNA nucleotide sequences and RNA fusions are chromosomal rearrangements that juxtapose two different genes together to form a fusion gene. The Afirma XA 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.

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, the expected impacts of Veracyte's collaboration with Johnson & Johnson in developing interventions for lung cancer, on Veracyte's financial and operating results, and on the size of Veracyte's addressable market. 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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