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Veracyte Announces Publication Highlighting Afirma GSC's Ability to Rule Out Cancer in Challenging Thyroid Nodule Subtype

RNA whole-transcriptome and machine learning platform enables genomic test to distinguishbenign Hürthle cells, reducing potential for unnecessary surgeries

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 8, 2019-- Veracyte, Inc. announced today that a new study published online in *BMC Systems Biology* showcases the development of the Afirma® Genomic Sequencing Classifier (GSC) and its ability to distinguish benign from likely-cancerous Hürthle cells, a common, but difficult-to-diagnose thyroid nodule subtype. The Afirma GSC was developed using Veracyte's novel RNA whole-transcriptome sequencing and machine learning platform. Most Hürthle cell cases yield inconclusive cytopathology results and, prior to Veracyte's next-generation genomic test, most of these patients typically required surgery to rule out thyroid cancer.

"While most Hürthle cells in patients with indeterminate thyroid nodules are benign, patients with this thyroid nodule subtype have historically been recommended for surgery because of the possibility of cancer," said Richard T. Kloos, M.D., senior medical director – endocrinology, at Veracyte. "Our novel science and technology platform enables the Afirma GSC to distinguish benign Hürthle cells and thus help rule out the need for surgery for many of these patients."

The new paper details the Afirma GSC's development and includes previously reported clinical validation findings showing that the Afirma GSC's ability to identify benign Hürthle-cell nodules increased by nearly five-fold compared to Veracyte's original Afirma Gene Expression Classifier (GEC). The next-generation test also maintains the flagship Afirma test's high sensitivity (91 percent), while identifying 30 percent more benign nodules (68 percent specificity) – regardless of thyroid subtype.

"This new paper supports the real-world results that we have observed in our practice since we began using the Afirma GSC in August 2017," said R. Mack Harrell, M.D., of the Memorial Center for Integrative Endocrine Surgery in Boca Raton, Fla. "We recently reported that, among Hürthle-cell dominant thyroid nodules, which comprise about 20 percent of all indeterminate nodules in our practice, the Afirma GSC has significantly increased the number of benign nodules that we've identified. Using the Afirma GSC test allows us to send 45 percent fewer patients to surgery, compared to the original Afirma GEC test, for an absolute reduction in surgeries of 25 percent. This is great news for our patients and for the healthcare system."

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 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 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 three 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. Examples of forward-looking statements include, among others, the ability of Veracyte's Afirma GSC to identify Hürthle cells, the expected impacts of Veracyte's collaboration with Johnson & Johnson in developing interventions for lung cancer, on Veracyte's financial and operating results, on the timing of the commercialization of the Percepta classifier, 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 annual report on Form 10-K for the year ended December 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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