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Veracyte Announces New Data Suggesting Afirma Testing Can Help Personalize Care for Patients with Thyroid Nodules

Findings published in Frontiers in Endocrinology *were derived from analyses of Veracyte's comprehensive thyroid nodule database of whole transcriptome sequencing*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 1, 2023-- Veracyte, Inc. (Nasdaq: VCYT) today announced that data published in *Frontiers in Endocrinology* provide new insights into the frequency and risk of malignancy (ROM) associated with thyroid stimulating hormone receptor (TSHR) mutations in indeterminate thyroid nodules. The findings, which were derived from analyses of Veracyte's comprehensive thyroid nodule database of whole transcriptome sequencing, suggest that the use of Afirma testing could help inform diagnoses and personalized treatment decisions for patients with thyroid nodules.

"We wanted to assess the frequency and risk of malignancy of TSHR mutations in indeterminate thyroid nodules, as well as how the risk of malignancy differs among those nodules classified by the Afirma Genomic Sequencing Classifier as suspicious for cancer versus benign," said Joyce Shin, M.D., endocrine surgeon and surgical director of the Thyroid Center, Cleveland Clinic, and an author on the study. "Our results suggest that TSHR mutations are rare and mostly associated with benign Afirma GSC classification; however, when coupled with an Afirma GSC 'suspicious' result, the risk of malignancy is significantly higher. This finding, from the largest cohort of TSHR-mutated indeterminate thyroid nodules evaluated to date, suggests that Afirma testing may provide clinically meaningful risk-stratification for patients whose thyroid nodules have this mutation."

Dr. Shin and colleagues evaluated indeterminate thyroid nodules that had undergone Afirma GSC testing and RNA sequencing analysis, and found that 8,881 had a TSHR variant, representing 5.4% of all samples collected over the study period. Of these, only 5% were classified as suspicious for cancer by the Afirma GSC. Among those nodules classified by the Afirma GSC as benign, the risk of malignancy is expected to be less than or equal to 4%, similar to a cytologically benign nodule where conservative follow-up is preferred. However, researchers found that when the Afirma GSC identified a thyroid nodule with a TSHR mutation as suspicious, the risk of malignancy was 15.3%, a level of risk for which most physicians would likely recommend at least active surveillance of the nodule, if not a diagnostic thyroid lobectomy procedure.

"These findings underscore the significant potential of our expansive thyroid nodule database and whole-transcriptome capabilities to derive insights that may further enhance the ability of Afirma testing to help personalize care for patients with thyroid nodules," said Joshua Klopper, M.D., Veracyte's medical director, Endocrinology.

About the Afirma GSC

Veracyte estimates that each year approximately 565,000 people undergo fine-needle aspiration (FNA) biopsy evaluation for potentially cancerous thyroid nodules and that more than 110,000 of these patients receive indeterminate results – meaning their nodules are not clearly benign or malignant based on traditional cytopathology evaluation. Historically, most of these patients were directed to diagnostic surgery, even though 70% to 80% of the time, the nodules proved to be benign. The Afirma Genomic Sequencing Classifier (GSC) helps physicians identify patients with benign thyroid nodules among those with indeterminate FNA results, so that they may avoid unnecessary thyroid surgery. The test was developed with RNA whole-transcriptome sequencing and machine learning technology to provide physicians with clinically actionable results from the same FNA biopsy used for initial cytopathology. As part of the Afirma offering, the Xpression Atlas provides genomic alteration content from the same FNA samples used in Afirma GSC testing to help physicians decide, with greater confidence, on the surgical or therapeutic approach for their patients.

About Veracyte

Veracyte is a global diagnostics company whose vision is to transform cancer care for patients all over the world. We empower clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Our high-performing tests enable clinicians to make more confident diagnostic, prognostic, and treatment decisions for some of the most challenging diseases such as thyroid, prostate, breast, bladder and lung cancers, as well as interstitial lung diseases. We help patients avoid unnecessary procedures and speed time to diagnosis and appropriate treatment. In addition to making our tests available in the U.S. through our central laboratories, our exclusive license to a best-in-class diagnostics instrument (the nCounter Analysis System) positions us to deliver our tests to patients worldwide through laboratories that can perform them locally. 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, including, but not limited to our statements related to our plans, objectives, expectations (financial and otherwise) or intentions with respect to our clinical tests in and outside of the United States. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "positioned," "designed" and similar references to future periods. An example of forward-looking statements include, among others, that the Afirma GSC and Veracyte's gene-expression based signatures have the potential to help personalize care and therapy decisions for patients with thyroid nodules. Additional factors that may impact these forward-looking statements can be found under the caption "Risk Factors" in our Annual Report on Form 10-K filed on February 28, 2022, and our Quarterly Report on Form 10-Q filed for the three months ended September 30, 2022. Copies of these documents, when available, may be found in the Investors section of our website at www.investor.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, we specifically disclaim 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.

Veracyte delivers the Afirma Genomic Sequencing Classifier and Xpression Atlas from its CLIA laboratory. These tests are not CE-IVD marked and have not been cleared or approved by the FDA; their performance characteristics were determined by Veracyte and they might be considered for Research Use Only in some markets. Please contact Veracyte for confirmation. This piece is distributed purely for educational purposes and is not intended to promote or encourage any off-label use of Veracyte products.

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