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New Data Show Strong Performance of Veracyte's Afirma GSC in Real-World Clinical Practice

Meta-analysis of independent, real-world studies was presented at ENDO 2022 and shows even better Afirma GSC performance compared to original clinical validation study

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 20, 2022-- Veracyte, Inc. (Nasdaq: VCYT) today announced that findings from a new meta-analysis provide real-world evidence that the Afirma Genomic Sequencing Classifier (GSC) can accurately rule out thyroid cancer in patients with indeterminate thyroid nodules and that, when the test deems a nodule as suspicious, the patient's risk of malignancy is consistent, and higher than that reported in the test's original clinical validation (CV) study. The findings were presented for the first time at the ENDO 2022 Annual Conference (Poster LBSAT255).

"The Afirma GSC's clinical validation study provided high-quality evidence of our test's ability to rule out malignancy in indeterminate thyroid nodules to help these patients avoid unnecessary surgery. Our new findings show that the real-world experience supports this data, further demonstrating that the likelihood of malignancy in Afirma GSC-suspicious nodules is even greater than what was reported in the validation study," said Joshua Klopper, M.D., Veracyte's medical director for endocrinology and an author on the study.

In the new meta-analysis, researchers evaluated 13 independent studies and found that the Afirma GSC's real-world ability to identify benign nodules with high sensitivity and high negative predictive value for thyroid cancer was similar to the CV study results (97 percent vs. 91 percent and 99 percent vs. 96 percent, respectively). Additionally, the meta-analysis data show that the Afirma test's real-world performance surpasses that shown in the CV study when predicting the risk of malignancy in nodules labeled suspicious (65 percent positive predictive value vs. 47 percent).

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 percent to 80 percent of the time, the nodules proved to be benign. Current American Thyroid Association guidelines include molecular testing as a recommended option to achieve definitive diagnosis for nodules classified as indeterminate following FNA biopsy.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company that improves patient care by answering important clinical questions to inform diagnosis and treatment decisions. Our growing menu of advanced diagnostic tests help patients avoid risky, costly procedures and interventions, and reduce time to appropriate treatment. Our tests address eight of the 10 most prevalent cancers by incidence in the United States. In addition to making our tests available in the United States through our central laboratories, our exclusive license to a best-in-class diagnostics instrument 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 the Afirma GSC. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will," "prospective" and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. An example of a forward-looking statement includes, among others, that the Afirma GSC can improve thyroid cancer diagnosis in patients with indeterminate 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 with the SEC on February 28, 2022, and our subsequent quarterly reports on Form 10-Q. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. These forward-looking statements speak only as of the date hereof and, except as required by law, 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.

The Afirma GSC is available as part of Veracyte's CLIA-validated laboratory developed test (LDT) service. The test has not been cleared or approved by the FDA. Veracyte, the Veracyte logo and Afirma are registered trademarks of Veracyte, Inc. and its subsidiaries in the U.S. and selected countries.

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