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New Data Being Presented at AACE 2023 Help Elucidate Cancer Risk of TERT Promoter Gene Mutations in Patients with Indeterminate Thyroid Nodules

Findings reinforce value of Veracyte's expanded Afirma offering, which now includes TERT gene mutation testing

SOUTH SAN FRANCISCO--(BUSINESS WIRE)--May 4, 2023-- Veracyte, Inc. (Nasdaq: VCYT) announced findings from a large-scale, systematic literature review showing that *TERT* promoter gene mutations in thyroid nodules deemed indeterminate by cytopathology are rare, but have a high risk of malignancy and, in certain cases, are associated with aggressive tumor behavior. The data are being presented at the American Association of Clinical Endocrinology (AACE) 2023 Annual Meeting, being held May 4-6 in Seattle, and reinforce the value of Veracyte's expanded Afirma offering, which now includes *TERT* promoter mutation testing.

For the study, Veracyte and external researchers systematically searched and reviewed 26 manuscripts published between 2014 and 2022 and identified a total of 77 *TERT* promoter-mutated indeterminate thyroid nodules with histologic correlates. They then calculated the risk of malignancy for all nodules, as well as the risk for those with isolated *TERT* promoter mutations, and with co-mutations in the *RAS* family of genes and with *BRAF*V600E. When relevant information was available, the researchers also determined the proportion of aggressive cancers in each group based on the tumors' histopathology findings.

Overall, 84% of *TERT* promoter-mutated indeterminate nodules were malignant. There was no difference in the malignancy rate of nodules with isolated *TERT* promoter mutations compared to those with *TERT* promoter + *RAS* family co-mutations, nor was there a difference in the proportion of cancers with aggressive histology between these two groups. Of the five *TERT* promoter + *BRAF*V600E co-mutated nodules, all were malignant and 60% were described as aggressive.

"Our findings suggest that while *TERT* promoter mutations are rare in indeterminate thyroid nodules, when they occur, they are associated with a high risk of malignancy," said Joshua Klopper, M.D., medical director of Endocrinology at Veracyte. "Additionally, our analysis reinforces recent literature suggesting that *TERT* promoter mutations co-occurring with the *BRAF*V600E variant are likely to be associated with a poor prognosis. These results provide an important foundation for further research to understand whether patients with *TERT* promoter-mutated indeterminate thyroid nodules should receive aggressive initial treatment."

The new study findings underscore the value of Veracyte's recent expansion of its Afirma offering to include *TERT* promoter mutation testing, with a goal of helping physicians further personalize diagnosis and treatment for their patients with thyroid nodules.

"The addition of *TERT* mutation testing to our Afirma platform reflects the growing significance of these mutations in the literature and underscores our focus on continual product innovation to further empower physicians to provide optimal care for their patients with thyroid nodules," said Dr. Klopper.

The company's flagship Afirma Genomic Sequencing Classifier (GSC) was developed with RNA sequencing and machine learning technology and helps physicians identify patients with benign thyroid nodules among those whose fine needle aspiration (FNA) biopsy results are indeterminate by cytopathology so that they can potentially avoid unnecessary thyroid surgery. The Afirma GSC also includes the Xpression Atlas, the largest thyroid gene and fusion variant panel available, to help inform treatment decisions for patients whose genomic test or cytopathology results are suspicious for cancer. With its expanded offering, Veracyte enables physicians to order DNA testing of the *TERT* promoter gene, which is performed on the same FNA sample, to help further guide treatment decision-making.

About Veracyte

Veracyte (Nasdaq: VCYT) 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, we also aim to deliver our tests to patients worldwide through a distributed model to laboratories that can perform them locally. 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. Examples of forward-looking statements include, among others, that the addition of TERT mutation testing to the Afirma offering may help further inform treatment decisions for thyroid nodule patients. 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 22, 2023, and our Quarterly Report on Form 10-Q filed for the three months ended December 31, 2022. Copies of these documents, when available, may be found in the Investors section of our website at https://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 TERT DNA analysis 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.

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