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Veracyte Announces New Clinical Validation Data for RNA Sequencing-Based Afirma Medullary Thyroid Cancer Classifier Published in Thyroid

The Genomic Test Demonstrated 100 Percent Sensitivity and 100 Percent Specificity for MTC

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 20, 2022-- [Veracyte, Inc.](#) (Nasdaq: VCYT) today announced that new clinical validation data published online in [Thyroid](#) show that the company's RNA sequencing-based Afirma Medullary Thyroid Cancer (MTC) Classifier demonstrated high sensitivity and specificity in identifying MTC among pre-operative thyroid nodule fine needle aspiration (FNA) biopsy samples. The findings suggest that the genomic test may enable more timely diagnosis of this rare but aggressive form of thyroid cancer, compared to traditional methods, thus potentially expediting time to appropriate treatment.

The Afirma MTC Classifier is included as part of the Afirma testing offering on all orders for patients with thyroid nodules that are deemed indeterminate or suspicious for cancer based on cytopathology evaluation.

"MTC is often difficult to distinguish using traditional cytopathology," said Joshua Klopper, M.D., Veracyte's medical director for endocrinology and an author of the study. "However, knowing that a patient has this potentially aggressive type of thyroid cancer before surgery is important so that the physician can plan the surgery appropriately. Our findings show that the Afirma MTC Classifier identifies MTC on pre-operative samples with high accuracy, which may optimize patient outcomes."

For the study, researchers evaluated the Afirma MTC's performance on a blinded cohort of 211 pre-operative thyroid FNA samples with subsequent surgical pathology, including 21 MTC samples and 190 non-MTC samples that included both benign and malignant thyroid lesions. They found that the classifier accurately identified all 21 MTC cases (100 percent sensitivity) and all 190 non-MTC cases (100 percent specificity).

"These new data further reinforce the value that Afirma testing can offer in providing a clear diagnosis of MTC, which is so important for appropriate thyroid and nodal surgery to be done," said Gregory W. Randolph, M.D., director of the Thyroid and Parathyroid Endocrine Surgical Division at Mass Eye and Ear, professor at Harvard Medical School, and lead author on the study.

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 our clinical tests, assays, biopharma business opportunities and immuno-oncology offerings. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "suggest," "may," "will" "prospective," "potential" 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 MTC Classifier may enable more timely diagnosis of MTC, thus potentially expediting appropriate treatment. 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.

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Investors:

Shayla Gorman
Director, Investor Relations
investors@veracyte.com
619-393-1545

Media:

Tracy Morris
Vice President, Global Corporate Communications
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.