Veracyte Announces that New Afirma GRID Data Suggest Prognostic Ability of Molecular Testing for Thyroid Tumors

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Findings presented at the ENDO 2024 conference

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 3, 2024-- Veracyte, Inc. (Nasdaq: VCYT), a leading cancer diagnostics company, today announced new research findings suggesting the potential of novel molecular signatures to identify patients with thyroid nodules or cancer who have aggressive disease. The findings, which could potentially help clinicians further individualize care based on each patient's tumor biology, are derived from research using Veracyte's Afirma GRID (Genomic Resource for Intelligent Discovery) tool. The results were presented today at ENDO 2024, the annual meeting of The Endocrine Society in Boston.

"Clinicians generally want to avoid overtreatment of patients with non-aggressive thyroid tumors while targeting more-intensive treatment to those patients with aggressive disease. The challenge is distinguishing between them, especially given the heterogeneity of thyroid tumors," said Joshua Klopper, M.D., Veracyte's medical director for Endocrinology. "The studies presented at ENDO 2024 today show how our Research-Use-Only Afirma GRID tool, which leverages our whole-transcriptome-derived testing approach, is helping scientists better understand important nuances in the molecular underpinnings of thyroid tumors. These insights may ultimately enable more-personalized care for patients."

Following are highlights of the three Afirma GRID-focused studies presented at the ENDO 2024 conference:

- **Poster presentation (MON-640): Retrospective Analysis of mRNA Expression Based Signatures of Thyroid Tumor Invasion and Metastases. Presented by Sara Ahmadi, M.D., Brigham and Women's Hospital.**

  Summary: Researchers analyzed novel whole-transcriptome-based signatures, previously presented at the ENDO 2023 meeting, that were designed to help rule out significant thyroid tumor invasion or regional lymph node metastases in patients with indeterminate thyroid nodules. This was a retrospective study of 203 thyroid nodule patients with indeterminate cytology who had Afirma GSC-suspicious results and pathology results from subsequent thyroid surgery. The molecular signatures ruled out the clinically significant features in more than 50% of patients, with a greater than 95% negative predictive value.

  "Today, most patients with thyroid nodules that are suspicious for cancer are directed to surgery," said Sara Ahmadi, M.D., of Brigham and Women's Hospital who presented the findings. "Our results suggest that molecular testing may potentially help to further stratify risk so that clinicians could confidently perform a less-invasive surgical procedure that would reduce complications and potentially mitigate the need for lifelong thyroid hormone replacement therapy. While more study is needed, these findings are an exciting step towards the future of personalized medicine in thyroid nodules and cancer."

- **Oral presentation (OR28-04): Cancer-associated Fibroblasts Correlate with Aggressive Thyroid Cancer Behavior: Insights from Four Large Patient Cohorts. Presented by Matthew A. Loberg, B.A., Vanderbilt University Medical Center.**

  Summary: Researchers identified cancer-associated fibroblasts (CAFs) in the thyroid tumor microenvironment that correlate with aggression in thyroid cancers largely by leveraging the Afirma GRID database, which includes whole-transcriptome data derived from the Afirma assay. In this multicenter study involving nearly 50,000 patients, they identified CAFs for the first time in pre-operative fine needle aspiration (FNA) samples. Notably, they found that the *SFRP2*+ CAF was associated with shorter progression-free survival, tumor invasion and lymph node metastasis. It was also enriched in thyroid nodules that were deemed suspicious by the Afirma Genomic Sequencing Classifier (GSC) or Bethesda V/VI by cytopathology, compared to Afirma GSC-benign nodules. While more study is needed, such insights could potentially help inform more-personalized management strategies for patients with thyroid nodules or cancer.

- **Poster Presentation (MON-649) and Rapid-Fire Oral Presentation (RF28-01): Prostate-specific Membrane Antigen (PSMA) Expression in Cytologically Indeterminate and Malignant Thyroid Nodules. Presented by Rabail Sadiq, M.B.B.S., Johns Hopkins University School of Medicine.**

  Prostate-specific membrane antigen (PSMA) is a protein found on the surface of cancer cells and is increasingly used as a biomarker in prostate cancer detection and treatment. Higher PSMA levels have also been associated with more-aggressive thyroid cancers. Researchers leveraged the Afirma GRID database to characterize the expression of PSMA (*FOLH1*) in a cohort of nearly 50,000 thyroid nodules sent for Afirma GSC molecular testing. They found that PSMA gene expression was higher in indeterminate nodules that were Afirma GSC-suspicious and in nodules whose cytopathology was classified as Bethesda V/VI, compared to Afirma GSC-benign nodules. They also found variability in PSMA expression in the context of certain molecular driver mutations. The authors conclude that PSMA expression may potentially help provide further prognostic information to inform care for thyroid nodule patients.

"The studies presented at ENDO 2024 reinforce our commitment to not only developing high-performing tests, but also to helping the research

community advance the science around thyroid cancer and the other indications we serve," said Phillip Febbo, M.D., chief scientific officer and chief medical officer at Veracyte. "They also demonstrate the power of our Veracyte Diagnostics Platform, through which our comprehensive, whole-transcriptome-derived testing approach helps drive continued innovation to ultimately help more patients."

About Afirma GRID

The Afirma GRID database is derived from the sequencing of over 21,000 expressed genes for nearly 200,000 patients with thyroid nodules (benign and malignant) and is used by Veracyte and its partners to contribute to continued research that helps advance understanding of thyroid tumors. Afirma GRID information is available on a Research-Use-Only basis. More information about Afirma GRID can be found here.

About the Afirma GSC

Veracyte's flagship Afirma Genomic Sequencing Classifier (GSC) was developed with RNA whole-transcriptome-derived 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 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. Veracyte also 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. More information about the Afirma GSC can be found here.

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 Veracyte Diagnostics Platform delivers high-performing cancer tests that are fueled by broad genomic and clinical data, deep bioinformatic and AI capabilities, and a powerful evidence-generation engine, which ultimately drives durable reimbursement and guideline inclusion for our tests, along with new insights to support continued innovation and pipeline development. For more information, please visit www.veracyte.com and follow the company on X (formerly Twitter) at @veracyte.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to our statements related to the potential for the Afirma GRID research-use-only tool to help scientists better understand important nuances in the molecular underpinnings of thyroid tumors, such insights which may ultimately enable more-personalized care for patients. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "enable," "positioned," "offers," "designed," "ultimately," and similar references to future periods. Actual results may differ materially from those projected or suggested in any forward-looking statements. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to the potential impact Afirma GRID can have on scientific advancements in thyroid cancer and, in turn, 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 29, 2024, and our 10-Q filed on May 8, 2024. 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. 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.

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