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New Clinical Utility Data Confirm Veracyte's Envisia Genomic Classifier Increases Accuracy and Confidence in IPF Diagnosis

Findings to be shared in oral presentation at CHEST Annual Meeting 2021

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 11, 2021-- Veracyte, Inc. (Nasdaq: VCYT) announced new data demonstrating that the Envisia Genomic Classifier positively impacts clinical decision-making in idiopathic pulmonary fibrosis (IPF) by increasing diagnostic accuracy, physician confidence in diagnosis, and patient referral to appropriate therapy. The data, from a prospective, randomized decision-impact survey involving more than 100 pulmonologists, will be shared October 18 in an oral presentation at the American College of Chest Physicians (CHEST) Annual Meeting 2021 (Abstract #40063).

Veracyte estimates that each year in the United States and Europe approximately 200,000 patients have unclear results following evaluation for suspected interstitial lung diseases (ILDs), including IPF, which is among the most common, deadly and difficult to diagnose of these lung-scarring diseases. The Envisia Genomic Classifier is a highly accurate, clinically validated molecular test that detects a genomic pattern of usual interstitial pneumonia (UIP), a critical factor that can help physicians differentiate IPF from other ILDs.

"Physicians and patients need more objective, accurate tools to diagnose ILD and IPF so that patients can receive appropriate treatment and avoid further, invasive procedures such as surgical lung biopsy," said Marc Stapley, Veracyte's chief executive officer. "The new data being presented at CHEST next week suggest that the Envisia classifier can help address this long-standing clinical gap, enabling physicians and patients to make better, faster and more confident care decisions."

Researchers led by Joseph Lasky, M.D., of Tulane University Medical School surveyed 103 practicing pulmonologists to determine the impact of the Envisia classifier on clinical decision-making in IPF. Each survey participant received five patient cases from the BRAVE (Bronchial Sample Collection for a Novel Genomic Test) study and was asked to determine an ILD diagnosis, their confidence level in their diagnosis and the next management step. A cohort of 81 physicians initially reviewed cases without Envisia test results (pre-Envisia) and then again with the classifier results added (post-Envisia). Researchers randomly selected the patient cases from a set of 11 that all had undiagnosed ILD, a high-resolution computed tomography (HRCT) scan without a "typical" UIP pattern, and a UIP-positive Envisia test result, and had undergone multidisciplinary team discussion that resulted in a final diagnosis of IPF.

Results show that the Envisia classifier significantly increases IPF diagnosis, physicians' confidence in their diagnosis and recommendations for patients to initiate treatment. Among the cohort of 81 physicians who reviewed cases both pre- and post-Envisia (a total of 155 case reviews):

- IPF diagnosis increased by 39% from 47 (30%) pre-Envisia to 107 (69%) post-Envisia (Odds Ratio [OR]:16.43; Confidence Interval [CI]=7.52,41.96; p<0.001)
- IPF diagnoses increased from 4 (4.5%) to 48 (54.5%) pre- and post-Envisia among the subset of 88 patients who had an HRCT pattern that was indeterminate or most consistent with a non-IPF diagnosis (OR:30.4; CI=9.93,148.60; p<0.001)
- The number of physicians saying they had a high level of confidence in their diagnosis (≥90%) increased from 9 (5.8%) pre-Envisia to 65 (42%) post-Envisia (p<0.0001)
- The recommendation for patients to initiate treatment as the next step in IPF management increased from 19 (12%) pre-Envisia to 77 (50%) post-Envisia (OR:8.22; CI=4.45,15.20; p<0.001)
- Recommendation for obtaining a SLB or cryobiopsy significantly decreased from 40 (26%) pre- Envisia to 26 (17%) post-Envisia (OR:0.49; CI=0.25,0.92; p=0.03)

"Given the progressive nature of IPF, accurate, timely diagnosis and initiation of antifibrotic therapy for patients who may benefit is critical," said Dr. Lasky, who will present the study results at the CHEST meeting. "These findings suggest that the Envisia classifier can facilitate this difficult diagnosis, potentially enabling physicians to more effectively care for patients and improve their outcomes."

About Veracyte

Veracyte (Nasdaq: VCYT) is a global diagnostics company that improves patient care by providing answers to clinical questions, informing diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The company's growing menu of diagnostic tests leverages advances in genomic science and technology, enabling patients to avoid risky, costly diagnostic procedures and quicken time to appropriate treatment. The company's tests in lung cancer, prostate cancer, breast cancer, thyroid cancer, bladder cancer, colon cancer, and idiopathic pulmonary fibrosis are available to patients and its renal cancer and lymphoma subtyping tests are in development, the latter as a companion diagnostic. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its genomic tests to patients worldwide. 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 Envisia Genomic Classifier. 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. Examples of forward-looking statements include, among others, statements regarding Veracyte's belief that its Envisia Genomic Classifier can significantly improve the diagnosis of ILDs, including IPF, and

assist healthcare providers in selecting patient treatment options. 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 22, 2021 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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