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Envisia Genomic Classifier Highlighted in Updated Clinical Practice Guideline Regarding Idiopathic Pulmonary Fibrosis Diagnosis

Review article and commentary in* AnnalsATS *reinforce clinical utility of genomic test to improve confidence in IPF diagnosis, in conjunction with HRCT and clinical factors

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 2, 2022-- Veracyte, Inc. (Nasdaq: VCYT) announced today that an updated clinical practice guideline highlights the role of the Envisia Genomic Classifier in the diagnosis of idiopathic pulmonary fibrosis (IPF). The document, *Idiopathic Pulmonary Fibrosis (an Update) and Progressive Pulmonary Fibrosis in Adults: An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline,* appears online in the *American Journal of Respiratory and Critical Care Medicine (AJRCCM).* Additionally, a new review article and separate commentary on the Envisia Genomic Classifier appear online in *AnnalsATS*. *AJRCCM* and *AnnalsATS* are official journals of the American Thoracic Society.

“We are encouraged by the extensive discussion of the Envisia Genomic Classifier in this updated guideline and the related articles regarding diagnosis of IPF and other interstitial lung diseases,” said Giulia C. Kennedy, Ph.D., Veracyte’s global chief scientific officer and chief medical officer. “We believe these discussions reinforce the intended clinical value of our test, which is to enable physicians to make a confident diagnosis of IPF, without the need for invasive surgery.”

The Envisia classifier detects a genomic pattern of usual interstitial pneumonia (UIP), a critical factor that can help physicians differentiate IPF from other interstitial lung diseases (ILDs), without the need for surgery. The test was developed using RNA whole-transcriptome sequencing and machine learning and is covered by Medicare.

“IPF and other ILDs are often extremely challenging to diagnose,” said Fayez Kheir, M.D., a pulmonologist at Massachusetts General Hospital and lead author of the review article. “The Envisia test, with its ability to help rule in UIP, may help give physicians more confidence in an IPF diagnosis, when used in conjunction with HRCT and clinical factors. Having a confident IPF diagnosis is important because it can help these patients to obtain the therapy they need in a timely manner.”

More than 40 percent of the guideline authors voted to specifically recommend genomic classifier testing for use in clinical practice. According to the guideline, “Those who favored genomic classifier testing believed that the high specificity provided important diagnostic information that can be used in MDD [multi-disciplinary discussion] and, therefore, may reduce the need for additional sampling for histopathology diagnosis.”

The guideline points to a meta-analysis of data for the Envisia test, which showed a specificity for identifying a UIP pattern of 92 percent and a sensitivity of 68 percent in patients with an ILD of unknown type following clinical evaluation and high-resolution computed tomography (HRCT).

Approximately 200,000 patients are evaluated for suspected ILDs each year in the United States and Europe. ILDs are serious, lung-scarring diseases that are often difficult to diagnose; IPF is among the most common and dangerous of these illnesses. In a U.S. survey of people with ILDs including IPF, 55 percent of patients reported at least one misdiagnosis prior to receiving an accurate diagnosis and more than a third (38 percent) reported at least two misdiagnoses. This diagnostic challenge often leads to treatment delays, misdiagnoses, patient distress, and added healthcare expense. Accurate and timely diagnosis of IPF is especially important given the availability of drugs to slow progression of the disease.

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 throughout the patient journey. 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 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. An example of a forward-looking statement includes, among others, that the Envisia Genomic Classifier is designed to help physicians more accurately, quickly and confidently diagnose IPF. 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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