



November 5, 2021

Veracyte Announces Immunoscore Colon Cancer Test Included in ESMO Clinical Practice Guidelines Adapted for Pan-Asia

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 5, 2021-- [Veracyte, Inc.](#) (Nasdaq: VCYT) today announced that its Immunoscore Colon Cancer test has been included in the Pan-Asian adapted ESMO¹ Clinical Practice Guidelines for the diagnosis, treatment and follow-up of patients with localized colon cancer. The new guidelines appear online in [Annals of Oncology](#) and will be highlighted at the ESMO Asia Virtual Oncology Week 2021 meeting, being held November 17-23, 2021.

Veracyte acquired the Immunoscore Colon Cancer test through its acquisition of HlioDx in August 2021. The test measures patient immune response at the tumor site and is used to inform chemotherapy decision-making for patients with Stage II and III colon cancer.

The Immunoscore Colon Cancer test was included in the 2020 ESMO Clinical Practice Guidelines for Diagnosis, Treatment, and Follow-up of Colon Cancer. The new Pan-Asian guidelines take into account ethnic differences associated with the treatment of localized colon cancer in Asian patients. They comprise the consensus opinions reached by 14 experts representing the oncological societies of Japan, China, India, Korea, Malaysia, Singapore and Taiwan.

The 2020 ESMO guidelines and the new Pan-Asian adapted version both emphasize that tumor recurrence risk-assessment and expected benefit from chemotherapy are key to the evaluation of adjuvant therapy options. In this context, the Immunoscore Colon Cancer test is recommended for its ability to refine the prognosis of stage II and stage III colon cancer patients, in conjunction with standard cancer staging known as TNM (Tumor, Node, Metastasis).

"There is a need for standardization of approaches with the aim of optimizing clinical outcomes. The Immunoscore test is introduced in these guidelines in the Risk Assessment chapter as it provides a reliable estimate of risk of recurrence, when used in adjunct to standard TNM classification," said Dr. Josep Tabernero, of the Vall d'Hebron Institute of Oncology in Barcelona, Spain. "We are happy to have 100 percent consensus in these up-to-date pan-Asian guidelines for considering the use of the test in stage II and stage III disease."*

"We are pleased that Pan-Asian experts recognize the utility of the Immunoscore test in localized colon cancer," said Stephane Debono, general manager, Immunoscore and International Diagnostics Operations at Veracyte. "We consider this a significant milestone in our efforts to facilitate reimbursement for the test so that more patients may benefit from its ability to provide important information that may help guide treatment decisions."

According to the new ESMO Pan-Asian guidelines, recent estimates show Asia to account for half of the new cases, deaths and 5-year prevalence for colorectal cancer (CRC). Asian studies suggesting that individuals of Chinese, Japanese and Korean ethnicity might be more susceptible to CRC. CRC represents a major healthcare challenge across Asia, with the incidence predicted to increase sharply over the next decade.

About Immunoscore

The Immunoscore Colon Cancer test accurately measures patient immune response at the tumor site by providing a robust, precise, quantitative, and consensus assessment of lymphocytic infiltration in human tumors and has been shown to predict patient outcome in several indications. The test has been validated in an international study conducted on more than 2,500 Stage I-III colon cancer patients². This study showed that Immunoscore is a powerful and independent prognostic factor for patient survival which provided the greatest contribution to patient prognostication of all assessed factors. In validation studies of stage III colon cancers, the Immunoscore test provides information that may help physicians determine the optimal duration of FOLFOX treatment. In 2020, the test was included in the ESMO Clinical Practice Guidelines for Diagnosis, Treatment, and Follow-up of Colon Cancer and the World Health Organization (WHO), in its latest edition of the Digestive System Tumours, cited immune response as an essential and desirable diagnostic criterion for colorectal cancer, in addition to traditional histological parameters³. Immunoscore is commercially available in more than 20 countries. Immunoscore is CE-IVD marked. The test's results are delivered worldwide from Veracyte's CLIA laboratories.

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 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 Immunoscore. 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 the Immunoscore Colon Cancer test can assist in the treatment of localized colon cancer in Asian 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 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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¹ European Society of Medical Oncology

² Pagès F, et al. International validation of the consensus Immunoscore for the classification of colon cancer: a prognostic and accuracy study. *Lancet*. 2018 May 26;391(10135):2128-2139.

³ The World Health Organization is not endorsing the Immunoscore commercial assay.

**Reminder: The development of guidelines is a structured process related to a medical standpoint. Economic considerations for access and market availability are to be addressed distinctly in other appropriate frameworks.*

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Source: Veracyte, Inc.