Veracyte Announces In Vitro Diagnostic Agreement with Illumina to Broaden Availability of Its Tests for Patients Globally

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Agreement is part of Veracyte's multi-platform strategy for its decentralized IVD tests outside of the U.S.

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 7, 2023-- Veracyte, Inc. (Nasdaq: VCYT) today announced that it has entered into a multi-year agreement with Illumina, Inc. (Nasdaq: ILMN) to develop and offer some of its high-performing molecular tests as decentralized *in vitro* diagnostic (IVD) tests on Illumina's NextSeq 550Dx next-generation sequencing (NGS) instrument. The agreement is part of Veracyte's expanded, multi-platform IVD approach, which will also include qPCR and is designed to accelerate the company's ability to make its tests available to more patients globally.

"By expanding our IVD strategy to include established NGS and qPCR technologies, we believe we can help even more physicians and patients make better diagnostic and treatment decisions using our tests," said Marc Stapley, Veracyte's chief executive officer. "With its significant and growing installed base of NGS IVD instruments, Illumina is a natural partner to help us achieve our vision of transforming cancer care for patients all over the world."

The first tests that Veracyte plans to develop for the Illumina NextSeq 550Dx instrument are its Prosigna Breast Cancer Assay and Percepta Nasal Swab test. Prosigna is already commercially available as an IVD test that helps inform treatment decisions for patients with early-stage breast cancer. The noninvasive Percepta Nasal Swab test is intended to help guide diagnosis and treatment decisions for current and former smokers with lung nodules that are potentially cancerous.

"We are pleased to partner with Veracyte, with its high-performing tests in some of the world's most prevalent cancers, to expand the reach of NGS-based molecular testing in cancer care," said Joydeep Goswami, chief financial officer and chief corporate development and strategy officer of Illumina. "We believe that enabling hospitals and laboratories to perform advanced molecular testing locally will significantly broaden market access and enable faster turnaround times so that patients and physicians can make better informed and timely decisions."

Illumina's NextSeq 550Dx instrument offers a validated mid-throughput platform and provides access to an ever-expanding pipeline of clinical applications in the fields of oncology, reproductive health, genetic diseases testing, and more. With regulatory approvals in over 60 countries, NextSeq 550Dx has become a trusted platform for hospitals and clinical laboratories running a menu of high-quality diagnostic tests.

Veracyte is also developing its Decipher Prostate Genomic Classifier, currently available in the United States through its CLIA laboratory, as a qPCR-based test for use outside of the U.S.

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 high-performing tests enable clinicians to make more confident diagnostic, prognostic, and treatment decisions for some of the most challenging diseases such as thyroid, prostate, breast, bladder and lung cancers, as well as interstitial lung diseases. We help patients avoid unnecessary procedures and speed time to diagnosis and appropriate treatment. In addition to making our tests available in the U.S. through our central laboratories, we also aim to deliver our tests to patients worldwide through a distributed model to laboratories that can perform them locally. 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 in and outside of the United States. Forward-looking statements can be identified by word as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "positioned," "designed" and similar references to future periods. Examples of forward-looking statements include, among others, that this expanded platform strategy, including through the use of Illumina's NextSeq 550Dx, will accelerate the company's ability to make its tests available to more patients globally; that with this strategy, Veracyte can help even more physicians and patients make better diagnostic and treatment decisions using our tests; and that enabling hospitals and laboratories to perform advanced molecular testing locally will significantly broaden market access and enable faster turnaround times patients and physicians can make better informed and timely decisions. 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 March 1, 2023, and our Quarterly Report on Form 10-Q filed for the three months ended June 30, 2023. 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.

The Percepta Nasal Swab test and the Decipher Prostate Genomic Classifier are available in the US as part of Veracyte's CLIA-validated laboratory developed test (LDT) service. These tests have not been cleared or approved by the FDA.

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Veracyte Contacts

Investors:
investors@veracyte.com

619-393-1545

Media:
Tracy Morris
VP of Global Corporate Communications
tracy.morris@veracyte.com
650-380-4413

Source: Veracyte, Inc.