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Veracyte Announces Key Milestone in Companion Diagnostics Program With Acerta Pharma Using LymphMark Lymphoma Subtyping Test

First Patient Enrolled and Randomized in Study Utilizing LymphMark to Identify Patients with Untreated DLBCL Who May Potentially Benefit from Calquence in Combination with R-CHOP Therapy

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Apr. 14, 2021-- Veracyte (Nasdaq: VCYT) today announced a key milestone in its companion diagnostics program with Acerta Pharma, the hematology research and development arm of AstraZeneca (LSE/STO/NYSE: AZN). The first patient has been enrolled and randomized in Acerta Pharma's Phase 3 ESCALADE trial, which is using Veracyte's LymphMark lymphoma subtyping test to identify patients with untreated diffuse large B-cell lymphoma (DLBCL) who may benefit from Acerta and AstraZeneca's acalabrutinib (Calquence®) in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) therapy.

The randomized, double-blind, placebo-controlled ESCALADE study is designed to evaluate the efficacy and safety of acalabrutinib with R-CHOP therapy as compared to placebo plus R-CHOP in patients aged 18-65. The study is expected to enroll up to 600 participants at centers around the world. Study investigators are using the investigational LymphMark genomic test to select patients with non-germinal center B-cell (non-GCB) subtype DLBCL, an aggressive form of the disease that is associated with worse outcomes following the traditional chemoimmunotherapy regimen (R-CHOP).

"The initiation of this global study marks an important step in our multi-year companion diagnostics program with Acerta Pharma," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "By distinguishing DLBCL patients based on the genomic underpinning of their disease, we believe the LymphMark test will help identify patients early on who are more likely to respond to targeted therapies such as Calquence that may improve outcomes."

DLBCL patients respond to treatment differently based on the molecular subtype of their tumors. The LymphMark test uses gene-expression profiling of RNA extracted from surgical tissue to classify the "cell of origin" subtype of DLBCL tumors. The World Health Organization recommends gene-expression profiling for patients with DLBCL, which may potentially be mitigated by more specific treatments that are under development.[i] By identifying the specific subtypes in individual patients' tumors, physicians can help ensure the right patients are included in clinical trials evaluating these therapies.

Non-Hodgkin lymphoma (NHL) ranks among the top-10 common cancers worldwide, with over 500,000 new cases estimated in 2018.[ii] DLBCL is the most common type of NHL, accounting for approximately 30 percent of lymphomas.[iii]

The LymphMark test is intended for use on the nCounter Analysis System. Veracyte acquired the LymphMark test, as well as the exclusive global diagnostic rights to the nCounter system, in December 2019.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global genomic 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 genomic tests leverage 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 and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping and renal cancer tests are in development. 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, LymphMark's ability to identify patients suitable for inclusion in clinical trials, improve clinical care and patient outcomes, the ability of Acerta Pharma and AstraZeneca to enroll sufficient patients in clinical trials, and the expansion of Veracyte's test menu and use of the nCounter system. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "positioned," "designed" 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 performance of Veracyte's tests in the clinical environment. 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. The risks and uncertainties may be amplified by the COVID-19 pandemic, which has caused significant economic uncertainty. The extent to which the COVID-19 pandemic impacts Veracyte's businesses, operations, and financial results, including the duration and magnitude of such effects, will depend on numerous factors, which are unpredictable, including, but not limited to, the duration and spread of the outbreak, its severity, the actions to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume. 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.

[i] Swerdlow SH, Campo E, Pileri SA, et al. The 2016 revisions of the World Health Organization classification of lymphoid neoplasms. *Blood*. 2016;127(20):2375-2390.

[ii] Miranda-Filho A, Piñeros M, Znaor A, Marcos-Gragera R, Steliarova-Foucher E, Bray F. Global patterns and trends in the incidence of non-Hodgkin lymphoma. *Cancer Causes Control*. 2019;30(5):489-499. doi:10.1007/s10552-019-01155-5.

[iii] Types of B-cell Lymphoma. American Cancer Society. https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/b-cell-lymphoma.html. Accessed June 1, 2020.

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