



## **Adaptive Biotechnologies Announces Launch of clonoSEQ® to Assess Minimal Residual Disease (MRD) in Patients with Diffuse Large B-Cell Lymphoma (DLBCL) Using Circulating Tumor DNA (ctDNA)**

December 1, 2022

- *clonoSEQ is the first and only MRD test in DLBCL with Medicare coverage across all lines of therapy, treatment regimens, and timepoints*
- *Adaptive now accepts blood samples from DLBCL patients in Streck® tubes that stabilize ctDNA*

SEATTLE, Dec. 01, 2022 (GLOBE NEWSWIRE) -- Adaptive Biotechnologies Corporation (Nasdaq: ADPT), a commercial stage biotechnology company that aims to translate the genetics of the adaptive immune system into clinical products to diagnose and treat disease, today announced the launch of its clonoSEQ® Assay to detect minimal residual disease (MRD) in blood for patients with diffuse large B-cell lymphoma (DLBCL). DLBCL is the most common type of non-Hodgkin lymphoma (NHL), affecting more than 100,000 people in the U.S. Because DLBCL is an aggressive but also potentially curable disease for many patients, disease monitoring plays a central role in patient management.

clonoSEQ can assess a patient's MRD status in DLBCL by measuring ctDNA, the fragments of DNA released into the blood from dying cancer cells which can serve as a measure of tumor burden. clonoSEQ is available in DLBCL as a CLIA-validated laboratory developed test (LDT), and beginning this week the company will accept DLBCL blood samples in Streck® tubes, enabling broader access to ctDNA-based MRD testing for clinicians and patients.

"We are excited to continue to expand access to clonoSEQ as a highly specific and less invasive tool for DLBCL monitoring which will complement the current standard imaging methods," said Nitin Sood, chief commercial officer, MRD, Adaptive Biotechnologies. "By measuring ctDNA in blood, clonoSEQ provides clinicians with a sensitive and quantitative assessment of disease burden so that they can detect relapse sooner and are better equipped to create a more precise treatment plan for each patient."

clonoSEQ MRD testing is covered by Medicare in DLBCL, with coverage extending to all DLBCL patients regardless of line of therapy, treatment regimen, or testing timepoint. clonoSEQ is the first and only MRD test to receive Medicare coverage in DLBCL.

Robust peer-reviewed evidence supports the use of clonoSEQ as a powerful blood-based prognostic tool in DLBCL. Data published in the post-frontline surveillance setting, the transplant setting, and post-CART demonstrate the utility of clonoSEQ ctDNA assessment to accurately predict which patients are likely to relapse. When used in conjunction with or as a supplement to imaging-based methods established in clinical practice guidelines, clonoSEQ has the potential to help oncologists optimize DLBCL patient care.

"The continued development of new treatments for DLBCL requires novel, precise ways to monitor disease progression. Imaging is an important monitoring tool but also has known clinical limitations and drawbacks for patients," said Dr. Tara Graff, hematologist/oncologist at Mission Cancer and Blood. "clonoSEQ testing in blood can serve as a complement to imaging, aiding in my work-up and decision-making process for DLBCL patients and in some cases, helping spare patients from unnecessary procedures and treatments."

In addition to its availability as a CLIA-validated LDT in DLBCL in blood, clonoSEQ is also available as an FDA-cleared in vitro diagnostic (IVD) test service provided by Adaptive Biotechnologies to detect MRD in bone marrow from patients with multiple myeloma (MM) or B-cell acute lymphoblastic leukemia (B-ALL) and blood or bone marrow from patients with chronic lymphocytic leukemia (CLL).

### **About the clonoSEQ Assay**

The clonoSEQ Assay is the first and only FDA-cleared in vitro diagnostic (IVD) test service to detect minimal residual disease (MRD) in bone marrow from patients with multiple myeloma (MM) or B-cell acute lymphoblastic leukemia (B-ALL) and blood or bone marrow from patients with chronic lymphocytic leukemia (CLL). It is also clonoSEQ testing for diffuse large B-cell lymphoma (DLBCL) patients is currently available for clinical use as a laboratory-developed test (LDT) performed at Adaptive's CLIA-certified lab in Seattle, WA. clonoSEQ ctDNA-based MRD testing in DLBCL has also been approved by New York State's Clinical Laboratory Evaluation Program (CLEP). Medicare covers clonoSEQ in these four indications and is aligned with clinical practice guidelines which support assessing MRD at multiple time points throughout therapy to monitor treatment response and help predict patient outcomes.

The clonoSEQ Assay leverages Adaptive Biotechnologies' proprietary immune medicine platform to identify and quantify specific DNA sequences found in malignant cells, allowing clinicians to assess and monitor MRD during and after treatment. The assay provides standardized, accurate and sensitive measurement of MRD that allows physicians to predict patient outcomes, assess response to therapy over time, monitor patients during remission and predict potential relapse. Clinical practice guidelines in hematological malignancies recognize that MRD status is a reliable indicator of clinical outcomes and response to therapy, and clinical outcomes have been shown to be strongly associated with MRD levels measured by the clonoSEQ Assay in patients diagnosed with CLL, MM, ALL and DLBCL.

For important information about the FDA-cleared uses of clonoSEQ, including the full intended use, limitations, and detailed performance characteristics, please visit [www.clonoSEQ.com/technical-summary](http://www.clonoSEQ.com/technical-summary).

### **About Adaptive Biotechnologies**

Adaptive Biotechnologies ("we" or "our") is a commercial-stage biotechnology company focused on harnessing the inherent biology of the adaptive immune system to transform the diagnosis and treatment of disease. We believe the adaptive immune system is nature's most finely tuned diagnostic

and therapeutic for most diseases, but the inability to decode it has prevented the medical community from fully leveraging its capabilities. Our proprietary immune medicine platform reveals and translates the massive genetics of the adaptive immune system with scale, precision and speed. We apply our platform to partner with biopharmaceutical companies, inform drug development, and develop clinical diagnostics across our two business areas: Minimal Residual Disease (MRD) and Immune Medicine. Our commercial products and clinical pipeline enable the diagnosis, monitoring, and treatment of diseases such as cancer, autoimmune disorders, and infectious diseases. Our goal is to develop and commercialize immune-driven clinical products tailored to each individual patient.

#### **Forward-Looking Statements**

This press release contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize and achieve market acceptance of our current and planned products and services, our research and development efforts and other matters regarding our business strategies, use of capital, results of operations and financial position and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors are described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file with the Securities and Exchange Commission from time to time. We caution you that forward-looking statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent our views as of the date hereof. We undertake no obligation to update any forward-looking statements for any reason, except as required by law.

#### **ADAPTIVE MEDIA**

Mary Pat Lancelotta, Senior Vice President, Corporate Affairs and Communications

206-600-6702

[media@adaptivebiotech.com](mailto:media@adaptivebiotech.com)

#### **ADAPTIVE INVESTORS**

Karina Calzadilla, Vice President, Investor Relations

201-396-1687

[investors@adaptivebiotech.com](mailto:investors@adaptivebiotech.com)