Adaptive Biotechnologies Launches Assay Enhancements to Increase clonoSEQ® Sensitivity for Clinical MRD Detection in Diffuse Large B-Cell Lymphoma

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Enhanced assay granted approval by New York State's Clinical Lab Evaluation Program (CLEP) for patients with DLBCL

clonoSEQ is the only DLBCL MRD assay available for clinical use and covered by Medicare

SEATTLE, March 11, 2025 (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 that it has launched an upgraded version of its clonoSEQ assay for measurable residual disease (MRD) detection in diffuse large B-cell lymphoma (DLBCL) using circulating tumor DNA (ctDNA).

The enhanced clonoSEQ assay, which incorporates an optimized DNA extraction methodology and maximizes sample input, delivers a 7-fold increase in sensitivity. The assay leverages the same powerful technology as prior versions, detecting MRD by reading the full immune receptor sequence of the malignant B cells rather than relying on individual point mutations. Maintaining this proprietary approach enables improvements in sensitivity while preserving the exquisite specificity that minimizes risk of overtreatment due to false positives.

The enhanced assay was previously made available for research use in November 2023 and is already being incorporated into both biopharma-sponsored and investigator-initiated prospective trials. Data generated using this assay and presented at ASH 2024 by Bond and colleagues demonstrated that in patients for which MRD was assessed by clonoSEQ, MRD negativity post-cycle six was highly prognostic of progression-free survival.

"The enhancements to our clonoSEQ ctDNA-based DLBCL test offering strengthen the assay's already-deep clinical sensitivity without compromising our unparalleled specificity," said Susan Bobulsky, chief commercial officer, MRD, Adaptive Biotechnologies. "The assay's strong performance on both fronts makes it possible to deliver accurate, actionable insights in the clinic and empowers drug developers to precisely target treatment intensification strategies for patients who remain MRD-positive at end of frontline therapy while minimizing the risk of overtreatment."

clonoSEQ is the first and only DLBCL MRD test available for clinical use. Having secured Medicare coverage for clonoSEQ in DLBCL in July of 2022, Adaptive has since provided MRD testing for more than 2,800 DLBCL patients and was used to manage and inform patient care by over 640 providers in 2024 alone. The New York State Department of Health Clinical Laboratory Evaluation Program (CLEP) recently approved the enhanced version of the clonoSEQ ctDNA assay for the detection and monitoring of MRD in patients with DLBCL. This comes on the heels of the updated National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for B-Cell Lymphomas, which included language recommending ctDNA testing for MRD assessment for patients with PET-positive DLBCL at end of first-line treatment.

DLBCL is the most common form of non-Hodgkin lymphoma (NHL), accounting for about 1 out of every 3 NHL patients in the United States. More than 18,000 people are diagnosed with DLBCL each year. About 30–40% of patients will experience relapse, most of them within the first two years. MRD testing can help doctors assess treatment response, detect early signs of cancer recurrence, and adjust treatment plans.

Because DLBCL outcomes can vary widely following frontline treatment, the ability of MRD results to accurately risk stratify patients in this setting is critical, as an MRD test can help clinicians differentiate a likely cure from an impending relapse. As the number of clinical trials in DLBCL exploring novel MRD-directed treatment consolidation strategies to reduce relapse rates grows, the role for clonoSEQ as a highly sensitive and specific ctDNA-based test will continue to expand.

About clonoSEQ
clonoSEQ 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). clonoSEQ testing for patients with diffuse large B-cell lymphoma (DLBCL) is currently available for clinical use as a laboratory-developed test (LDT) performed at Adaptive's CLIA-certified lab in Seattle. clonoSEQ is CE-marked under the In Vitro Diagnostic Regulation (IVDR) in the European Union (EU). For the approved intended use in the EU under IVDR, please refer to the instructions for use, available on request.

clonoSEQ 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 treatment, inform changes in therapy, monitor disease burden over time, and detect potential relapse early. Clinical practice guidelines in hematologic 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 clonoSEQ in patients diagnosed with CLL, MM, B-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.

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 segments: Minimal Residual Disease (MRD) and Immune Medicine. Our commercial products and clinical pipeline enable the diagnosis, monitoring, and treatment of diseases such as cancer and autoimmune disorders. 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.

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