Adaptive Biotechnologies Receives Expanded Medicare Coverage of clonoSEQ® for Monitoring Minimal Residual Disease in Diffuse Large B-Cell Lymphoma

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clonoSEQ is the first and only assay to receive Medicare coverage for MRD assessment in DLBCL

SEATTLE, July 28, 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 that Palmetto GBA, a Medicare Administrative Contractor (MAC) that assesses diagnostic technologies through its MolDX program, has expanded coverage of the clonoSEQ® Assay to include monitoring minimal residual disease (MRD) in Medicare patients with diffuse large B-cell lymphoma (DLBCL), the most common type of non-Hodgkin lymphoma (NHL). This coverage determination is the first for clonoSEQ to include the assessment of MRD based on circulating tumor DNA (ctDNA), fragments of DNA released into the blood from lysed cancer cells.

MRD refers to the remaining number of cancer cells that may be present in a patient's body during and after treatment and that may eventually lead to recurrence of the disease. MRD testing is a simple blood test performed at multiple timepoints throughout a patient's cancer journey to assess prognosis, determine response to treatment, detect relapse, and inform care. MRD assessment in DLBCL utilizes ctDNA measured in peripheral blood to give oncologists a better understanding of which patients are at high-risk for recurrence and provide them with information to create a more precise treatment plan for each patient.

"We've advanced therapy for large B-cell lymphomas significantly in recent years; however, a considerable unmet need for highly specific, precise monitoring of disease progression during and after treatment remains," said Frederick Locke, M.D., chair, Department of Blood and Marrow Transplant and Cellular Immunotherapy, Moffitt Cancer Center. "Measurement of ctDNA to assess MRD provides additional information that can complement or improve upon insights from imaging and that can help inform clinical management."

The updated coverage policy expands DLBCL patient access to clonoSEQ MRD testing, as approximately 75% of actively treated DLBCL patients are Medicare aged. The policy is effective immediately and extends to all DLBCL patients, regardless of line of therapy, treatment regimen, or testing timepoint. clonoSEQ testing for 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).

"We believe clonoSEQ raises the bar for disease monitoring in DLBCL patients. Recent studies have shown that MRD assessment with clonoSEQ early post CAR-T treatment can be more informative than PET-CT in identifying patients who were at high risk for relapse," said Nitin Sood, chief commercial officer, MRD, Adaptive Biotechnologies. "The Medicare coverage decision provides greater access to clonoSEQ and acknowledges the mounting evidence for implementing routine clonoSEQ MRD assessment in DLBCL."

This coverage expansion adds to existing Medicare coverage for clonoSEQ in multiple myeloma, chronic lymphocytic leukemia (CLL) and B-cell acute lymphoblastic leukemia (ALL). Medicare coverage for clonoSEQ in these indications 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.

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). MRD refers to the small number of cancer cells that can stay in the body during and after treatment.

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 and ALL.

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
Adaptive Biotechnologies 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 to develop products in our Immune Medicine and Minimal Residual Disease (MRD) businesses. We have three commercial products and a robust clinical pipeline to diagnose, monitor and enable the treatment of diseases such as cancer, autoimmune conditions and infectious diseases. For more information, please visit adaptivebiotech.com and follow us on www.twitter.com/adaptivebiotech.

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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