



Adaptive Biotechnologies Receives Expanded Medicare Coverage of clonoSEQ® for Monitoring MRD in Patients With Chronic Lymphocytic Leukemia

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SEATTLE, Jan. 08, 2020 (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 MoIDX program, has expanded coverage of the clonoSEQ Assay to include monitoring minimal residual disease (MRD) in Medicare patients with chronic lymphocytic leukemia (CLL). This adds to existing Medicare coverage in B-cell acute lymphoblastic leukemia (ALL) and multiple myeloma, which was established in January 2019. Medicare coverage for clonoSEQ is aligned with clinical practice guidelines in covered disease states which support assessing MRD at multiple time points throughout therapy to monitor treatment response and help predict patient outcomes. This expanded coverage policy is effective immediately and continues the positive momentum for clonoSEQ with over 175M lives covered to date.

"Patients with CLL who achieve undetectable MRD have better outcomes than those with detectable MRD," said Javier Pinilla-Ibarz, M.D., Ph.D., Senior Member and Head of the Lymphoma program in the Department of Malignant Hematology at Moffit Cancer Center. "As newer therapies emerge for CLL that can help patients achieve very deep remissions, assessment of MRD can help guide clinical care by determining a patient's response to therapy and informing that patient's prognosis."

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 performed as a series of tests throughout a patient's cancer journey to monitor for remission, detect relapse, determine response to treatment and inform care. Controlled trials have shown that even the smallest amounts of residual disease significantly predict a patient's long-term clinical outcomes.

"Data are mounting to support the clinical benefits of MRD measurement in lymphomas and leukemias, including CLL, to help assess a patient's prognosis, measure response to therapy and inform treatment decisions," said Lance Baldo, chief medical officer, Adaptive Biotechnologies. "The Medicare coverage expansion validates this growing body of evidence and provides patients living with CLL greater access to highly sensitive, standardized MRD testing."

clonoSEQ is the only test authorized by the U.S. Food and Drug Administration (FDA) to detect and monitor minimal residual disease in any lymphoid cancer. At the 2019 American Society of Hematology (ASH) Annual Meeting, an unprecedented amount of data was presented demonstrating the clinical significance of MRD in blood cancers and further validating it as one of the strongest predictors of patient outcomes.

About the clonoSEQ Assay

The clonoSEQ Assay was granted de novo designation and marketing authorization by FDA for the detection and monitoring of minimal residual disease (MRD) in patients with multiple myeloma (MM) and B-cell acute lymphoblastic leukemia (ALL) using DNA from bone marrow samples. clonoSEQ is the first and only FDA-authorized *in vitro* diagnostic assay for MRD testing. It is also the first clinical diagnostic powered by immunosequencing to receive FDA clearance. clonoSEQ leverages Adaptive's proprietary immunosequencing 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 detect 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 are strongly associated with MRD levels measured by the clonoSEQ Assay in patients diagnosed with ALL and MM. More than 175 million people in the US now have access to clonoSEQ through Medicare and private payor coverage.

clonoSEQ is a single-site assay performed at Adaptive Biotechnologies. It is also available as a CLIA-regulated laboratory developed test (LDT) service for use in other lymphoid cancers. 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 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 life sciences research, clinical diagnostics, and drug discovery. We have two commercial products, and a robust clinical pipeline to diagnose, monitor and enable the treatment of diseases such as cancer, autoimmune conditions and infectious diseases. Our goal is to develop and commercialize immune-driven clinical products tailored to each individual patient. For more information, please visit adaptivebiotech.com.

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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