Adaptive Biotechnologies Receives Expanded Medicare Coverage of clonoSEQ® for Assessing Measurable Residual Disease in Mantle Cell Lymphoma

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

Coverage leverages new Medicare episode pricing established based on updated clonoSEQ gapfill rate

SEATTLE, Nov. 07, 2024 (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 Molecular Diagnostics Services Program (MolDX), has expanded coverage of clonoSEQ® to include detection and monitoring of measurable residual disease (MRD) in Medicare patients with mantle cell lymphoma (MCL).

MCL is a sub-type of non-Hodgkin lymphoma (NHL) with an annual incidence of approximately 4,000 cases per year in the United States.[1] It is an aggressive disease, and most patients will relapse repeatedly; some shortly after frontline therapy, while others as late as 15 years after initial remission.[2,3] Given this challenging and variable course of disease, it is critical to effectively assess depth of response in patients undergoing treatment and monitor for recurrence or disease progression following remission.

MRD, or the cancer cells that may remain in a patient's body during and after treatment, is assessed through a series of tests over a patient's cancer journey. In MCL, clonoSEQ is a minimally invasive, blood-based MRD testing option that can be used to assess response, understand prognosis, and monitor patients to detect molecular recurrence before clinical or radiographic relapse.

"The value of MRD in MCL has been demonstrated in studies and supported by experiences in our own clinical practice," said Anita Kumar, M.D., associate attending physician, Memorial Sloan Kettering Cancer Center. "New treatment strategies in MCL are improving the outlook for patients with this aggressive disease, creating a need for MRD insights as a complement to traditional MCL monitoring tools such as imaging. Access to highly sensitive, blood-based MRD testing will empower clinicians to more precisely monitor the quality and depth of response and remission, and more accurately predict clinical relapse."

This updated coverage policy significantly expands access to clonoSEQ MRD testing for patients being treated for MCL, as the majority are of Medicare age. The policy extends to all patients with MCL, regardless of line of therapy or treatment regimen. The MolDX coverage follows the existing Medicare episode payment structure utilized for all other covered clonoSEQ indications. Following the Clinical Laboratory Fee Schedule (CLFS) annual payment determination process, MolDX recently updated clonoSEQ episode pricing across all the currently covered indications to $8,029, in line with the gapfill rate recommended by Medicare Administrative Contractors. This coverage expansion adds to existing Medicare coverage for clonoSEQ, which includes cellular DNA-based MRD testing in multiple myeloma, chronic lymphocytic leukemia (CLL) and B-cell acute lymphoblastic leukemia (ALL) and circulating tumor DNA-based MRD testing in diffuse large B-cell lymphoma (DLBCL).

"In an incurable disease such as MCL, implementing clonoSEQ MRD assessment is essential not only to identify those patients at high risk of relapse but also for advancing patient-centric treatment interventions and multi-modal monitoring strategies," said Ben Eckert, senior vice president, Market Access, Adaptive Biotechnologies. "We're pleased with MolDX's decision to provide access to clonoSEQ for the MCL Medicare population, as coverage will enable further integration of this important tool into lymphoma care pathways and ultimately improve outcomes for patients."

clonoSEQ testing for patients with MCL is currently available for clinical use as a laboratory-developed test performed at Adaptive's CLIA-certified lab in Seattle. clonoSEQ testing in MCL has also been previously approved by New York State's Clinical Laboratory Evaluation Program (CLEP).

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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[3] Cheah CY, Seymour JF, Wang ML. Mantle cell lymphoma. *J Clin Oncol*. 2016;34(11):1256-1269.