Adaptive Biotechnologies Receives Expanded Medicare Coverage of clonoSEQ® for Surveillance in Mantle Cell Lymphoma

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clonoSEQ is now covered to monitor for recurrence in MCL patients who are in treatment-free remission

SEATTLE, April 08, 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 Palmetto GBA, a Medicare Administrative Contractor (MAC) that assesses diagnostic technologies through its Molecular Diagnostic Services Program (MolDX), has expanded coverage of clonoSEQ® to include single time point testing to monitor for recurrence in patients with a history of mantle cell lymphoma (MCL).

This expanded coverage is in addition to the existing Medicare episode payment structure for clonoSEQ, which provides coverage for a bundle of tests to assess response to therapy while a patient is being treated. Under the expanded coverage decision, patients who have completed treatment are now covered to receive clonoSEQ testing every six months for up to five years during treatment-free remission and annual testing thereafter until disease recurrence is detected. MCL is the first clonoSEQ indication to receive this determination and pricing will be consistent with the recently updated Clinical Laboratory Fee Schedule (CLFS) rate of $2,007 per clonoSEQ test.

“Securing coverage for clonoSEQ use in the MCL surveillance setting is a significant win for MCL patients. This coverage expansion enables clinicians to more effectively monitor and manage these patients who are at risk of relapse,” said Ben Eckert, senior vice president, Market Access, Adaptive Biotechnologies. “We believe this determination underscores the clinical utility of clonoSEQ testing and establishes a framework for potential expanded coverage of surveillance testing in other Medicare-covered clonoSEQ indications.”

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] MRD is assessed through a series of tests over an MCL patient’s cancer journey and leverages blood to assess response, understand prognosis, and monitor patients to detect molecular recurrence. With modern treatment regimens, most patients will achieve disease remission after completion of front-line therapy and maintenance. However, due to the nature of MCL, many patients eventually relapse, some as late as 15 years after initial remission. Therefore, ongoing recurrence monitoring is particularly important in MCL, and clonoSEQ MRD testing in blood provides longitudinal insights that can be used to limit or guide imaging in this setting.

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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[1] Kallam A, Vose J. Current treatments in mantle cell lymphoma. *Oncology*. 2023;37:326-333. https://www.cancernetwork.com/view/current-treatments-in-mantle-cell-lymphoma. Accessed November 5, 2024.