Adaptive Biotechnologies Announces Clinical Lab Fee Schedule Rate of $2,007 for clonoSEQ® Test for Minimal Residual Disease Assessment is Effective as of January 1st, 2025

January 7, 2025

SEATTLE, Jan. 07, 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, announced today that the new Medicare Clinical Laboratory Fee Schedule (CLFS) rate for its next-generation sequencing (NGS)-based clonoSEQ® test for minimal – or measurable – residual disease (MRD) assessment is now in effect as of January 1, 2025. The CLFS rate for clonoSEQ (PLA 0364U) was set at $2,007, consistent with the final gapfill rate recommendation for the test.

The CLFS, managed by the Centers for Medicare & Medicaid Services (CMS), establishes payment rates for lab tests covered by Medicare. Novel diagnostic laboratory tests like clonoSEQ, for which there is no existing comparable test, undergo a special pricing process known as gapfill determination. In this process, Medicare assesses the test's value by considering factors such as the resources required to perform the test, rates paid for the test by other payers, rates paid for tests leveraging similar technologies, and additional unique attributes of the test. After a year of evaluation, CMS finalizes a national rate to ensure that essential tests like clonoSEQ are fairly priced and accessible to patients who need them. Many other payers in the US look to the Medicare CLFS in establishing their rate schedules for diagnostic tests that they cover.

As previously announced, MolDX has also updated clonoSEQ episode pricing to $8,029, in line with this new CLFS rate across all covered indications, including multiple myeloma, chronic lymphocytic leukemia, B-cell acute lymphoblastic leukemia, circulating tumor DNA-based MRD testing in diffuse large B-cell lymphoma and mantle cell lymphoma.

"Finalizing the Medicare reimbursement rate for clonoSEQ through the gapfill process represents another key milestone and highlights the value of the test in patient care," said Ben Eckert, senior vice president, Market Access, Adaptive Biotechnologies. "MRD testing provides clinicians with essential insights into a patient's disease status and response to therapy. With the newly defined rate, we look forward to driving broader adoption by healthcare providers and private insurers, expanding accessibility for patients living with blood cancers."

The clonoSEQ test provides accurate and sensitive measurement of MRD in lymphoid malignancies and is widely covered by both Medicare and commercial payers for patients with lymphoid cancers. With the completion of the CLFS pricing process for clonoSEQ, Adaptive plans to leverage the finalized rate in the process of establishing new payer agreements, updating existing agreements to include the clonoSEQ PLA code, and expanding coverage to additional indications.

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 diffuse large B-cell lymphoma (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 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 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 clonoSEQ in patients diagnosed with CLL, MM, ALL, DLBCL and MCL.

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

ADAPTIVE INVESTORS
Karina Calzadilla, Vice President, Investor Relations
201-396-1687
investors@adaptivebiotech.com

ADAPTIVE MEDIA
Erica Jones, Associate Corporate Communications Director
206-279-2423
media@adaptivebiotech.com