Adaptive Biotechnologies Announces New Data at the 66th ASH Annual Meeting Highlighting Advances in MRD Testing with clonoSEQ® and Its Impact on Blood Cancer Treatment Decisions

December 7, 2024

New data demonstrate the actionability of clonoSEQ for tailoring treatment decisions in patients with MCL, CLL, MM and ALL

Studies show depth of response at 10^{-6} provides more accurate assessment of treatment responses

SEATTLE, Dec. 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 new data demonstrating the impact of measurable residual disease (MRD) assessment using Adaptive's next-generation sequencing-based clonoSEQ® test in blood cancer clinical care and drug development. The data are featured in more than 65 abstracts being presented at the 66th Annual Meeting of the American Society of Hematology (ASH), taking place December 6-10 in San Diego.

"At this year's ASH meeting, we're proud to see clonoSEQ's pivotal role in shaping the future of blood cancer care," said Susan Bobulsky, chief commercial officer, MRD, Adaptive Biotechnologies. "The breadth of data presented highlight the growing recognition of clonoSEQ as a powerful tool for accelerating patient access to novel therapies, optimizing clinical care and delivering actionable insights that improve outcomes for patients living with a variety of blood cancers."

Phase 3 data from the ECOG-ACRIN EA4151 trial indicate that autologous hematopoietic cell transplantation (auto-HCT) may not provide additional benefit for mantle cell lymphoma (MCL) patients in first complete remission (CR) who have undetectable minimal residual disease (uMRD) at a sensitivity of 10^{-6}. The findings will be presented in a late-breaking abstract titled, ***Lack of Benefit of Autologous Hematopoietic Cell Transplantation (auto-HCT) in Mantle Cell Lymphoma (MCL) Patients (pts) in First Complete Remission (CR) with Undetectable Minimal Residual Disease (uMRD): Initial Report from the ECOG-ACRIN EA4151 Phase 3 Randomized Trial (Abstract LBA6).*** Patients in CR with uMRD at 10^{-6} sensitivity from peripheral blood were randomized to receive either auto-HCT plus three years of maintenance rituximab (MR) or MR alone. Interim analysis, with a median follow-up of 2.7 years, showed no significant difference in overall survival (OS) between the two groups, suggesting that auto-HCT may be unnecessary for patients achieving deep remission as measured by highly sensitive MRD assessment.

"Our study indicates that highly sensitive MRD testing, such as the clonoSEQ assay that we used, can potentially be used to tailor treatment decisions for patients with MCL," said Timothy Fenske, M.D., professor, department of medicine, Medical College of Wisconsin. "By identifying patients in first complete remission who also have undetectable MRD status at 10^{-6}, we can potentially avoid the need for autologous hematopoietic cell transplantation, sparing them the associated risks and burdens. At the same time, patients who remain MRD-positive post-induction may benefit from more intensive consolidation therapy such as auto-HCT to optimize their outcomes."

Data from the FELIX study indicate that achieving deep molecular remission, defined as MRD levels below 10^{-6}, correlates with improved outcomes in adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia (B-ALL) treated with obecabtagene autoleucel. These findings were presented in an oral session titled ***Obecabtagene autoleucel (obe-cel) for Adult Relapsed/Refractory B-Cell Acute Lymphoblastic Leukemia (R/R B-ALL): Deep Molecular Remission May Predict Better Outcomes (Abstract 963).*** The study found that 84% of treatment responders who had a clonoSEQ MRD test, achieved MRD $<10^{-6}$. This result was associated with more durable responses, and higher event-free survival and OS rates than those observed in patients with MRD $\geq 10^{-4}$ and between 10^{-4} and 10^{-6}.

"Highly sensitive MRD testing provides a more accurate assessment of treatment response, allowing clinicians to make more informed decisions that can lead to improved long-term outcomes," said Elias Jabbour, M.D., professor of medicine, department of leukemia, The University of Texas MD Anderson Cancer Center. "The findings from the FELIX study underscore the importance of incorporating highly sensitive MRD testing into routine clinical practice to optimize care for patients."

Additional Key clonoSEQ Data Presented at the Meeting:

Blinatumomab Added to Chemotherapy Improves Disease-Free Survival in Newly Diagnosed NCI Standard Risk Pediatric B-Acute Lymphoblastic Leukemia: Results from the Randomized Children's Oncology Group Study AALL1731 (Abstract 1)

- This Phase 3 randomized trial evaluated the addition of blinatumomab to standard chemotherapy in pediatric patients with newly diagnosed standard-risk (SR) B-ALL with average or higher risk of relapse. In the SR average cohort, patients that were MRD positive by clonoSEQ were randomized to receive standard chemotherapy with or without blinatumomab. The study found that incorporating blinatumomab significantly improved disease-free survival compared to chemotherapy alone, establishing a new treatment standard for this patient population.

Implications of MRD Progression in Newly Diagnosed Multiple Myeloma (NDMM) Treated with Quadruplet Therapy and Autologous Stem Cell Transplantation (Abstract 363)

- This study identified 49 newly diagnosed multiple myeloma (MM) patients treated with a quadruplet regimen followed by autologous stem cell transplantation who experienced MRD progression as assessed by clonoSEQ, or disease progression as defined by the International Myeloma Working Group (IMWG). The median time from MRD progression to IMWG-defined disease progression was 10.1 months, supporting that rising MRD levels are an early indicator of impending

clinical relapse in MM patients.

Minimal Residual Disease (MRD)-Adapted Duration of Front-Line Venetoclax and Obinutuzumab Treatment for Fit Patients with Chronic Lymphocytic Leukemia (CLL) (Abstract 1010)

- This Phase 2 study evaluating the use of venetoclax and obinutuzumab in treatment-naïve CLL patients found that those achieving undetectable MRD ($<10^{-6}$) after nine cycles could discontinue therapy early. These patients had progression-free survival comparable to those who completed the standard 12 cycles, demonstrating the feasibility of MRD-guided treatment duration to minimize therapy exposure without compromising efficacy.

About clonoSEQ
clonoSEQ is the first and only FDA-cleared in vitro diagnostic (IVD) test 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) and mantle cell lymphoma (MCL) patients is currently available for clinical use as a laboratory-developed test (LDT) performed at Adaptive's CLIA-certified lab in Seattle, WA. clonoSEQ is CE-marked under IVDR in the 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 test 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 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 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.

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

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