Adaptive Biotechnologies Announces New Data Highlighting the Clinical Relevance of MRD Testing with clonoSEQ® in Patients with Blood Cancers at the 65th ASH Annual Meeting

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- *Treatment adapted studies show the potential for MRD assessment to guide the personalization of blood cancer care*
- *New data demonstrates MRD assessed from blood in multiple myeloma may be an indicator of early response*

SEATTLE, Dec. 09, 2023 (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 expanding use of Adaptive's next-generation sequencing (NGS)-based clonoSEQ ® test in assessing minimal residual disease (MRD) in blood cancer patient care and in clinical trials. The data are being presented in more than 30 abstracts at the 65th Annual Meeting of the American Society of Hematology (ASH), December 9-12 in San Diego, California.

Minimal residual disease, also known as measurable residual disease, refers to the residual malignant cells that can be present in the body after treatment at very low levels and can only be identified by highly sensitive tests. clonoSEQ, which is the only FDA-cleared test for MRD assessment in lymphoid malignancies, is highly accurate, sensitive, and standardized compared to other technologies used for disease burden assessment.

"The already-substantial body of evidence supporting clonoSEQ's prognostic value and clinical actionability is expanding in several important ways at ASH this year," said Susan Bobulsky, Senior Vice President, Diagnostics, Adaptive Biotechnologies. "We are pleased to see many studies presented elucidating the role of clonoSEQ MRD testing in blood – both in multiple myeloma, where blood-based testing can expand patient access to MRD insights, and in a variety of subtypes of non-Hodgkin lymphoma, such as mantle cell lymphoma, where we see promising evidence of the role MRD may play in informing management."

Data generated from the University of Chicago found that MRD status determined through clonoSEQ testing of the peripheral blood (PB) early in treatment was prognostic, while stratification by complete response (CR) was not. The data were presented in a poster presentation titled, ***Early Peripheral Blood Minimal Residual Disease Status by NGS in Patients with Newly Diagnosed Multiple Myeloma (MM) on a Phase 2 Trial Receiving Elotuzumab, Carfilzomib, Lenalidomide, and Dexamethasone (Elo-KRd) (Abstract 1982)***. The study evaluated matched bone marrow (BM) and PB samples from 31 newly diagnosed multiple myeloma patients at the end of cycle 4 of induction therapy. At this timepoint, MRD status from both PB and BM were similarly prognostic of patients' progression-free survival (PFS).

"We're encouraged to see the results of MRD testing with clonoSEQ in peripheral blood, which suggest that it is a prognostically significant assessment early in treatment," said Ben Derman, MD, Assistant Professor of Medicine at the University of Chicago. "The ability to gather early information from a blood test may be beneficial because bone marrow aspirate is not always sampled this early in treatment and an early indication of disease status may help inform downstream patient care decisions."

In an MRD-adapted study from the University of Wisconsin, MRD status assessed by clonoSEQ in peripheral blood was used to determine the relationship between early response and outcomes, as well as to guide maintenance therapy in patients with previously untreated mantle cell lymphoma (MCL). The data were presented in a poster presentation titled ***Minimal Residual Disease (MRD) Testing by Next Generation Sequencing (NGS) after Two Cycles (CY) of Non-Intensive Chemoimmunotherapy Is Predictive of Remission Duration and Need for Maintenance Therapy (MT) in Previously Untreated Mantle Cell Lymphoma (MCL): A Wisconsin Oncology Network Study (Abstract 4407).*** In this study of 21 patients, those with a CR who were MRD negative by clonoSEQ after induction and consolidation therapy were not given maintenance therapy. In patients without a CR or with persistent MRD positivity, obinutuzumab maintenance was given for 8 cycles. Patients were followed for ≥2 years from therapy completion. In patients achieving MRD negative status after induction and consolidation, omission of obinutuzumab maintenance did not result in worsening PFS compared to those that did receive maintenance. Additionally, MRD status post cycle 2 of induction was prognostic.

"The prognostic power of MRD has been well-substantiated, and now, a growing set of evidence supports the use of MRD to adapt approaches to therapy, with potentially meaningful implications on patients' quality of life," said Julie Chang, MD, Associate Professor, Hematology/Oncology Faculty, University of Wisconsin-Madison School of Medicine and Public Health. "In MCL, for patients that have an MRD negative test after initial therapy, avoiding additional treatment is not associated with worse outcomes. This has the potential to reduce the toxicities and financial burden for patients associated with maintenance treatment."

Additional Key clonoSEQ Data Presented at the Meeting:

Phase Ib/II Study of Multi-Targeted Therapy with Venetoclax, Ibrutinib, Prednisone, Obinutuzumab, and Lenalidomide (ViPOR) in Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL) (Abstract 434)

- In this study, clonoSEQ was used to monitor ctDNA following 6 cycles of ViPOR in 50 R/R DLBCL patients. Inferior PFS and overall survival (OS) were associated with an elevated ctDNA at baseline and detectable ctDNA during or at end of treatment, reinforcing the prognostic value of clonoSEQ in DLBCL.

A Multicenter Phase 2 Trial of Zanubrutinib, Obinutuzumab, and Venetoclax (BOVen) in Patients with Treatment-Naive, TP53-Mutant Mantle Cell Lymphoma (Abstract 738)

- This study investigated the efficacy and tolerability of the BOVen regimen (zanubrutinib [Zanu], Obinutuzumab [Obin], and venetoclax [Ven]) in high-risk MCL patients. Study outcomes included PFS and OS; MRD was assessed by clonoSEQ in peripheral blood. Patients who achieved complete remission and undetectable MRD after 24 cycles of BOVen discontinued treatment. This study shows how MRD assessment can identify deep responses to novel treatment regimens. Additionally, future outcomes data will elucidate the utility of MRD to guide treatment discontinuation in this population.

Post-CAR-T Minimal Residual Disease (MRD) Monitoring in Mantle Cell Lymphoma Enables Early Relapse Detection (Abstract 1673)

- In this real-world experience study, clonoSEQ was used to assess MRD in 34 MCL patients treated with brexu-cel. MRD positive patients had lower median PFS (10.74 months vs. 17.69 months) and 6 out of 7 relapses were preceded by an MRD positive test. 88% (15/17) of patients that were MRD negative at day 28 remained MRD negative at 6 months. This data reinforces that MRD status is a strong prognostic marker for relapse and durable remissions.

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 and DLBCL.

For important information about the FDA-cleared uses of clonoSEQ, including sample types and test limitations, 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.

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