Adaptive Biotechnologies Highlights New Data Showcasing the Clinical Utility of clonoSEQ® MRD Testing in Patients with Blood Cancers at the 64th ASH Annual Meeting

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- *Multiple presentations reinforce clonoSEQ's ability to provide valuable insights for treatment surveillance and clinical decision-making*
- *More than 30 clonoSEQ-related abstracts to be presented at the meeting*

SEATTLE, Dec. 10, 2022 (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 strengths of Adaptive's next-generation sequencing (NGS)-based clonoSEQ ® Assay in measuring minimal residual disease (MRD) in blood cancer patients. The data are being presented at the 64th Annual Meeting of the American Society of Hematology (ASH) taking place December 10-13, 2022.

MRD refers to the small number of cancer cells that can remain in a patient's body after treatment, which often cause no signs or symptoms but eventually can lead to recurrence of the disease. These residual cells can be present 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.

"Data at this year's ASH meeting continue to show the benefits of serial MRD measurement for blood cancer patients both in routine patient care and in clinical trials," said Nitin Sood, chief commercial officer, MRD, Adaptive Biotechnologies. "Multiple studies presented at ASH reinforce that clonoSEQ MRD results can play an important role in some of the most challenging decisions clinicians must make on a daily basis, such as whether and when to stop treatment."

Real-world evidence generated from the University of Alabama, Birmingham, demonstrated the feasibility of MRD testing with clonoSEQ to guide treatment decisions. The data were presented in a poster presentation titled, ***Induction Quadruplet Therapy and Minimal/Measurable Residual Disease (MRD)-Informed Treatment Adaptation in Newly Diagnosed Multiple Myeloma (NDMM): Results from an Academic-Community Pathway (Abstract 3593).*** The study adopted a modified treatment approach from the MASTER trial and evaluated 69 patients who were treated with the combination of daratumumab, Velcade, carfilzomib, lenalidomide and dexamethasone (mDara-VRd). MRD was assessed utilizing clonoSEQ at multiple timepoints. Of 42 patients with trackable MRD and >12 months post initiation of therapy,16 patients (38%) achieved two consecutive MRD-negative results <10^{-5}, which facilitated subsequent treatment discontinuation and entry into the MRD surveillance (MRD-SURE) phase of the study.

"We are encouraged by these real-world results, which suggest that monitoring MRD closely at multiple time points can impact informed decision-making regarding discontinuation of maintenance therapy for patients with MM," said Gayathri Ravi, MD, Principal Investigator from O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham. "Evidence supporting MRD-based treatment decisions has been mounting in clinical trials and academic centers, so we are pleased this study shows the feasibility of this prognostic approach in the community clinical setting in coordination with an academic center. A long duration of maintenance therapy can have a negative impact on patients – studies have shown most patients are unable or unwilling to stay on maintenance therapy indefinitely. An MRD-informed approach to treatment discontinuation that can relieve them of that burden is critical for real-world patient management."

Similar to the study above, data generated from the prospective MRD2STOP study indicates that MRD testing with clonoSEQ may help identify patients with MM who can discontinue maintenance therapy. The data were presented in an oral presentation titled, ***Prospective Trial Using Multimodal Measurable Residual Disease Negativity to Guide Discontinuation of Maintenance Therapy in Multiple Myeloma (MRD2STOP) (Abstract 870).*** The study evaluated discontinuation of maintenance in 38 MM patients with a median duration of consolidation or maintenance therapy of 42 months prior to discontinuation. To date, MRD resurgence at the 10^{-6} threshold was only identified in 5 (13%) patients, which included only two patients with disease progression. The rate of sustained MRD negativity (10^{-6}) at 12 months was 84%. This implies that discontinuation of maintenance therapy based on MRD assessment was accompanied by high rates of sustained MRD negativity and lack of disease progression. In an exploratory goal for the study, we show that performing clonoSEQ on CD138+-selection of bone marrow aspirate samples not only appear to improve the depth of MRD testing to 10^{-7} but also predict which patients may experience disease resurgence if they undergo discontinuation of all therapy. Longer follow-up studies are in progress.

"This study reinforces that MRD status is an important tool to help predict disease progression in MM, especially when considering de-escalation of therapy," said Ben Derman, MD, Assistant Professor of Medicine at the University of Chicago. "Precise measurement of MRD negativity is proving to be key in knowing whether a treatment is effectively producing a deep and durable response. We look forward to continuing this study and implementing MRD-informed decisions to determine duration of maintenance as standard-of-care."

Additional Key clonoSEQ Data Presented at the Meeting:

Outcomes of MRD-Adapted Treatment Modulation in Patients with Newly Diagnosed Multiple Myeloma Receiving Daratumumab, Carfilzomib, Lenalidomide and Dexamethasone (Dara-KRd) and Autologous Transplantation: Extended Follow up of the Master Trial (Abstract 3237)

- This study investigated the possibility of discontinuing maintenance therapy by measuring MRD negativity with the clonoSEQ Assay. Patients were treated with the combination of daratumumab, carfilzomib, lenalidomide and dexamethasone (Dara-KRd).
- The study concludes that for the majority of patients in the study without ultra-high-risk disease, MRD response-adapted treatment provided the opportunity to discontinue maintenance therapy without compromising disease control. The median follow-up in the study post therapy discontinuation was 24.8 months.

Immunoglobulin High Throughput Sequencing (Ig-HTS) Minimal Residual Disease (MRD) Analysis Is an Effective Surveillance Tool in Patients with Mantle Cell Lymphoma (Abstract 4806)

- This study conducted retrospective data collection and an analysis of outcomes in patients who underwent first-line treatment for mantle cell lymphoma (MCL) and were then monitored post-treatment using the clonoSEQ Assay.
- The data suggest that the clonoSEQ Assay is an effective surveillance tool for MCL patients following first-line therapy. Based on the data, clonoSEQ was predictive of relapse prior to imaging in all but one patient. In addition, the assay allowed for minimization of surveillance imaging, and early detection of MRD allowed for pre-emptive rituximab therapy in select patients.

Venetoclax, Ibrutinib, Prednisone, Obinutuzumab, and Lenalidomide (ViPOR) in Relapsed and Refractory Follicular Lymphoma: Analysis of Safety, Efficacy, and Minimal Residual Disease (Abstract 952)

- This analysis focused on data from patients with relapsed and refractory (r/r) follicular lymphoma (FL) treated with the ViPOR regimen. Response was assessed using imaging and MRD assessment from ctDNA with clonoSEQ.
- The results showed 88% of patients in complete remission were MRD-negative at the end of their treatment, and their MRD status was predictive of progression-free survival.

About the clonoSEQ Assay
The clonoSEQ Assay 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 ctDNA-based MRD testing in DLBCL has also been approved by New York State's Clinical Laboratory Evaluation Program (CLEP). Medicare covers clonoSEQ in these four indications and is aligned with clinical practice guidelines which support assessing MRD at multiple time points throughout therapy to monitor treatment response and help predict patient outcomes.

The clonoSEQ Assay 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 therapy over time, monitor patients during remission, and predict potential relapse. 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 the clonoSEQ Assay in patients diagnosed with CLL, MM, 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.

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