# Adaptive Biotechnologies Announces New Data Demonstrating the Benefit of Serial MRD Testing with the clonoSEQ® Assay in Patients with Blood Cancers at the 63rd ASH Annual Meeting

December 13, 2021

- *Analysis of the MASTER trial (Abstract 481) showed clonoSEQ's ability to measure deep and durable responses and permit treatment discontinuation in multiple myeloma patients*

- *Data in more than 30 abstracts supports clonoSEQ as a standard of care in blood cancers, delivering relevant and timely clinical insights to physicians, patients and investigators*

SEATTLE, Dec. 13, 2021 (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 highlighting the clinical utility of Adaptive's next-generation sequencing (NGS)-based clonoSEQ ® Assay to assess minimal residual disease (MRD) in patients with multiple myeloma (MM) and chronic lymphocytic leukemia (CLL). The data are being presented at the American Society of Hematology (ASH) 63rd Annual Meeting and Exposition, held December 11-14 as a hybrid event, in Atlanta and virtually.

MRD refers to the cancer cells that can remain in a patient's body after treatment. MRD may not cause symptoms, but the presence of even a small number of cells may ultimately predict clinical relapse. These residual cells can be present at very low levels and require highly sensitive tests like clonoSEQ to identify them.

Data generated from an analysis of the MASTER trial showed that regularly evaluating the MRD status of patients with newly diagnosed MM (NDMM) allowed confident and successful treatment discontinuation. This data was presented in an oral presentation titled, ***"Daratumumab, Carfilzomib, Lenalidomide and Dexamethasone (Dara-KRd), Autologous Transplantation and MRD Response-Adapted Consolidation and Treatment Cessation. Final Primary Endpoint Analysis of the Master Trial" (Abstract 481).*** The study evaluated 123 patients who were treated with the combination of daratumumab, carfilzomib, lenalidomide and dexamethasone (Dara-KRd) over 30 months. MRD was assessed utilizing clonoSEQ in 118 patients. Of those, 84 patients (71%) 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. MRD follow-up for MRD-SURE patients occurred at six months after treatment cessation and then on an annual basis. At 12 months post treatment cessation, the risk of MRD resurgence was 4% for patients with standard or high-risk cytogenetic abnormalities (HRCA).

"Ongoing assessment of MRD status is critical in multiple myeloma and should be considered as a part of every physician's treatment plan. We were thrilled to see that so many patients in this study achieved deep MRD-negative responses and were therefore able to stop treatment knowing that disease recurrence could be closely monitored," said Luciano Costa, MD, PhD, Principal Investigator from O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham. "As evidenced by this data, MRD can guide therapy. The resulting relief from the burden of ongoing maintenance therapy has the potential for profound impact on myeloma patients' quality of life."

In Phase 2 results from a poster presentation titled, ***"Zanubrutinib, Obinutuzumab, and Venetoclax in Chronic Lymphocytic Leukemia: Early MRD Kinetics Define a High-Risk Patient Cohort with Delayed Bone Marrow Undetectable MRD and Earlier Post-Treatment MRD Recurrence" (Abstract 3753)***, undetectable MRD (uMRD) was assessed from the peripheral blood (PB) and bone marrow (BM) of 39 patients with relapsed or refractory CLL to determine the duration of a regimen including zanubrutinib, obinutuzumab and venetoclax (BOVen). 33 patients stopped therapy based on predefined uMRD criteria. Of those, 94% remained MRD-negative after a median of 15 months without treatment. clonoSEQ was used to demonstrate that a >400-fold decrease in MRD from PB after 4 months was highly predictive of achieving uMRD in the BM in <8 months. These data support further investigation of the use of kinetics of early response with clonoSEQ to discontinue therapy.

"We found that BOVen achieved frequent, durable uMRD responses in previously untreated patients with CLL, with 89% of patients achieving uMRD in both the blood and bone marrow and stopping therapy after a median of 10 months," said Jacob Soumerai, MD, Center for Lymphoma, Massachusetts General Hospital Cancer Center. "Importantly, the MRD kinetics data presented at ASH suggest that it's not just whether or not you achieve uMRD, but rather that early MRD response kinetics might predict MRD outcomes and define biologic differences."

clonoSEQ represents a standard of care in MRD assessment, as evidenced by a significant volume of clonoSEQ data presented at the 2021 ASH Annual Meeting, including 22 various studies by pharmaceutical companies leveraging MRD with clonoSEQ to determine depth of response and stratify patient risk across blood cancers. Notably, clonoSEQ was used to measure deep and durable responses in patients in both the GLOW study (Abstract 70) and GRIFFIN study (Abstract 79).

"We are pleased to see clonoSEQ being used as the standard for MRD assessment in so many important presentations at this year's ASH annual meeting," said Lance Baldo, MD, Chief Medical Officer of Adaptive Biotechnologies. "Understanding MRD levels and trends over time is critical to the care of patients living with blood cancers, and clonoSEQ's unique ability to deliver sensitive, specific and standardized MRD results has proven valuable in informing treatment decisions, including extending and discontinuing therapy, that lead to excellent patient outcomes across multiple types of blood cancers."

**About the clonoSEQ Assay**
The clonoSEQ Assay is the first and only FDA-cleared assay for MRD in chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and B-cell acute lymphoblastic leukemia (ALL). Minimal residual disease (MRD) refers to the small number of cancer cells that can stay in the body during and after treatment. clonoSEQ was initially granted De Novo designation and marketing authorization by the FDA for the detection and monitoring of MRD in

patients with MM and ALL using DNA from bone marrow samples. In August 2020, clonoSEQ received additional clearance from the FDA to detect and monitor MRD in blood or bone marrow from patients with CLL.

The clonoSEQ Assay leverages Adaptive's 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 and ALL.

The clonoSEQ Assay is a single-site test performed at Adaptive Biotechnologies. In addition to its FDA-cleared uses, clonoSEQ is also available as a CLIA-validated laboratory developed test (LDT) service for MRD assessment in other lymphoid cancers and sample types, as well as for determination of IGHV mutation status in CLL/SLL patients. 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 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 to develop products in life sciences research, clinical diagnostics and drug discovery. We have three commercial products and a robust clinical pipeline to diagnose, monitor and enable the treatment of diseases such as cancer, autoimmune conditions and infectious diseases. Our goal is to develop and commercialize immune-driven clinical products tailored to each individual patient. For more information, please visit adaptivebiotech.com and follow us on www.twitter.com/adaptivebiotech.

**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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