Adaptive Biotechnologies Announces New Clinical Data Demonstrating Impact of clonoSEQ® Assay on Patients with Blood Cancers at the 62nd ASH Annual Meeting

December 6, 2020

MRD assessment with clonoSEQ improves outcomes both for patients and the healthcare system, as patients with undetectable MRD may be able to discontinue active treatment

SEATTLE, Dec. 06, 2020 (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 real-world data highlighting the clinical utility of Adaptive's next-generation sequencing (NGS) clonoSEQ ® Assay to assess minimal residual disease (MRD) in patients with multiple myeloma. The data are being presented at the American Society of Hematology (ASH) 62nd Annual Meeting and Exposition, held virtually December 5-8. Additional study results demonstrating the impact of Adaptive's clonoSEQ Assay in chronic lymphocytic leukemia (CLL), acute lymphoblastic leukemia (ALL) and mantle cell lymphoma (MCL) are also being presented at the meeting in 45 other abstracts.

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 require highly sensitive tests to identify them. clonoSEQ, which is the only FDA-cleared test for MRD assessment in lymphoid malignancies, is highly accurate, sensitive, and standardized compared to other technologies.

"The data presented at ASH this year reflect the growing evidence supporting clonoSEQ's ability to provide meaningful benefit for patients with blood cancers in a variety of clinical settings," said Lance Baldo, MD, Chief Medical Officer of Adaptive Biotechnologies. "It is increasingly clear that MRD testing with clonoSEQ, utilizing our immune medicine platform, is playing an important role in treatment decision-making which can have a dramatic impact not only on patients, but could also enable cost savings for the healthcare system overall."

Real-world evidence generated by clinicians at the University of California San Francisco (UCSF) and in Madrid demonstrated that MRD-based decision-making with the clonoSEQ Assay improved outcomes for multiple myeloma patients. This study will be presented in a poster presentation titled, ***"Making Clinical Decisions to Change Therapy Using Measurable Residual Disease Improves the Outcome in Multiple Myeloma"*** **(Abstract 2273).** The retrospective review evaluated 373 multiple myeloma patients from three health centers who had at least one MRD assessment. Of the 373 patients, physicians made a clinical decision to change treatment for 58 patients based on their MRD status. Results showed that these 58 patients had a significantly improved progression-free survival (PFS) versus patients who did not change treatment (n=312) (median PFS 97 vs. 75 months, p=0.006).

"We are encouraged by these real-world data and the impact MRD testing can have on the way we manage patients who have had great but not perfect responses to therapy, and the way we can make earlier decisions," said Jeffrey Wolf, MD, Clinical Professor, Department of Medicine, UCSF; and Director, Myeloma Program, UCSF Helen Diller Family Comprehensive Cancer Center. "These results support the integration of MRD assessment as a standard of care in the management of multiple myeloma patients. MRD assessment allows physicians and patients alike to have more confidence in their treatment decisions."

Myeloma patient advocates agree that there are meaningful, practical real-world benefits for patients who undergo MRD testing.

"The ability to accurately monitor disease burden in multiple myeloma is critical when making decisions that impact each patient's care," said Daniel Auclair, PhD, Chief Scientific Officer of the Multiple Myeloma Research Foundation. "We are encouraged by the data emerging in MRD assessment, which we believe will help myeloma patients and their doctors better manage their disease."

Patients may also benefit from potential MRD-informed treatment changes which may reduce the cost of their care. Additionally, researchers from the Winship Cancer Institute of Emory University will present results from a poster presentation titled **"*Cost-Effectiveness of Implementing clonoSEQ NGS-MRD Testing Using the Emory MRD Decision Protocol in Multiple Myeloma*" (Abstract 3426).** This study evaluated a framework which allowed patients with sustained MRD negativity (defined as MRD $<10^{-5}$ across two assessments at least 12-months apart) to discontinue indefinite maintenance therapy. Results showed that, based on savings of maintenance therapy costs or no longer requiring active treatment for relapsed/refractory (R/R) disease, MRD testing with clonoSEQ provided estimated lifetime savings of $916,000 per patient annually for the institution. Additionally, results showed MRD testing with clonoSEQ resulted in improved health outcomes in comparison to no testing (0.009 QALYs), primarily due to the avoidance of treatment-related adverse events.

Additional Key clonoSEQ Data Presented at the Meeting:

Monitoring Measurable Residual Disease Using Peripheral Blood in Acute Lymphoblastic Leukemia: Results of a Prospective, Observational Study (Abstract 975)

- This prospective study investigated the prognostic and predictive utility of peripheral blood (PB) based MRD assessment in 62 ALL patients who received a cellular therapy.
- The study demonstrated a strong correlation between MRD assessed from PB and bone marrow (BM) using clonoSEQ, and concluded that less-invasive clonoSEQ MRD monitoring in PB represents an alternative to serial BM examinations in patients undergoing curative intent cellular therapies.

Clonal Dynamics after Venetoclax-Obinutuzumab Therapy: Novel Insights from the Randomized, Phase 3 CLL14 Trial (Abstract 127)

- This Phase 3 study evaluated MRD as a secondary endpoint in 432 CLL patients with previously untreated CLL and co-existing conditions who were randomized to receive chlorambucil or venetoclax in combination with obinutuzumab. MRD was assessed every 3-6 months in PB. The subset of data presented at ASH analyzes MRD and clonal growth patterns in both cohorts of patients to better understand disease dynamics during and after treatment.
- Results showed that clonal growth, a measure for how quickly cancer cells grow, was significantly lower after treatment with venetoclax plus obinutuzumab than after treatment with chlorambucil and obinutuzumab, indicating more effective MRD eradication and clonal growth modulation with venetoclax plus obinutuzumab. Additionally, 40% of patients in the venetoclax arm had undetectable MRD levels of <10-6 compared to just 7% of patients in the chlorambucil arm.
- This analysis of the trial data demonstrates that understanding patient-specific cancer growth rates in addition to MRD status may be helpful in informing treatment duration.

Frontline Sequential Immunochemotherapy Plus Lenalidomide for Mantle Cell Lymphoma Incorporating MRD Evaluation: Phase II, Investigator-Initiated, Single-Center Study (Abstract 119)

- This study evaluated frontline sequential immunochemotherapy plus lenalidomide for the treatment of patients with MCL.
- During the study, MRD testing with clonoSEQ was performed on PB after each phase of treatment and at six months post end of treatment.
- There was a high rate of MRD negativity after induction chemoimmunotherapy (Len-R-CHOP + R-HiDAC) at thresholds of 10^{-5} (97%) and 10^{-6} (80%), with the deepest responses (10^{-6}) shown to be predictive of remission duration. Several patients converted from MRD-negative to MRD-positive at six months post-treatment and eventually relapsed, suggesting that a more prolonged period of maintenance may be beneficial.

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 B-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 use in other lymphoid cancers and sample types. 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
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 two 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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