Adaptive Biotechnologies Receives Expanded FDA Clearance for the clonoSEQ® Assay to Assess Minimal Residual Disease (MRD) in Patients with Chronic Lymphocytic Leukemia

August 6, 2020

- First and only FDA-cleared assay for MRD in CLL, multiple myeloma and ALL
- CLL clearance includes testing in blood; Adaptive collaborating with LabCorp® and Phlebotek Solutions® to provide clonoSEQ patients convenient options and safe access to blood draws at home or at LabCorp Patient Service Centers

A Media Snippet accompanying this announcement is available by clicking on the image or link below:

Adaptive Biotechnologies Receives Expanded FDA Clearance for the clonoSEQ® Assay to Assess Minimal Residual Disease (MRD) in Patients with Chronic Lymphocytic Leukemia: Media Snippet

SEATTLE, Aug. 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 received clearance from the U.S. Food and Drug Administration (FDA) for its clonoSEQ® Assay to detect and monitor minimal residual disease (MRD) in blood or bone marrow from patients with chronic lymphocytic leukemia (CLL). clonoSEQ is the first and only FDA-cleared in vitro diagnostic for MRD monitoring in CLL. Today's clearance expands the existing FDA-cleared uses of clonoSEQ, as the FDA previously granted the assay De Novo designation for the detection and monitoring of MRD in bone marrow from multiple myeloma and B-cell acute lymphoblastic leukemia (ALL) patients.

Access to clonoSEQ for CLL patients nationwide is supported by the already-established Medicare coverage of clonoSEQ in CLL, as well as by the FDA's clearance of clonoSEQ testing for CLL patients in blood and marrow. Medicare coverage is critically important in CLL, as nearly 80 percent of patients living with CLL in the U.S. are of Medicare age. clonoSEQ's ability to detect MRD in blood provides CLL patients and health care providers with a more convenient and less intrusive option to monitor disease burden.

"FDA clearance of clonoSEQ, which can detect one single cancer cell among a million healthy cells, is an important milestone for the CLL community," said Dr. Brian Koffman, Chief Medical Officer and EVP of the CLL Society, Inc. "Looking with greater accuracy for persistent cancer cells can show how well treatment is working and may help inform important decisions such as changing or stopping therapy. In my own CLL journey, knowing my clonoSEQ MRD status has impacted the way my expert team of doctors and I manage my disease."

FDA clearance of clonoSEQ in CLL was based on clinical validation data from two important clinical trials:

- In an analysis of data from the CLL14 study (n=337), patients with undetectable MRD in blood by clonoSEQ at three months post-treatment had a nearly seven-fold reduced risk of disease progression compared with patients who did not reach undetectable MRD. For purposes of this analysis, an undetectable MRD was defined at a level of 1 cancer cell among one hundred thousand healthy cells (10^{-5}).
- Additional evaluation of the data showed that at 30 months post-treatment, the probability of disease progression for evaluable patients with undetectable MRD was only 5%, as compared to 36% for patients with detectable disease.
- In a second study by Thompson et al, clonoSEQ MRD results were shown to be significantly predictive of outcomes in both blood and bone marrow samples, regardless of the threshold at which MRD was assessed.

MRD refers to the remaining number of cancer cells that are present in a patient's body during and after treatment, which may eventually lead to recurrence of the disease. MRD assessment is performed as a series of tests throughout a patient's cancer journey to evaluate prognosis, determine response to treatment, monitor disease during remission and predict potential relapse. Controlled trials in CLL as well as other blood cancers have shown that even the smallest amounts of residual disease can predict a patient's long-term clinical outcomes. As novel therapies make deeper and more durable responses achievable for many blood cancer patients, clinicians are increasingly utilizing MRD results to help guide day-to-day patient management.

"We know that traditional CLL treatment response criteria are insufficient, so the ability to measure MRD with a test that is one hundred times more sensitive than standard flow cytometry may change our approach to treating CLL," said Dr. John Pagel, principal investigator and Chief of Hematologic Malignancies at the Swedish Cancer Institute. "A patient's MRD status gives us timely information about how a treatment is working, so patients and providers can be in the driver's seat when it comes to managing their disease and treatment decisions."

The availability of clonoSEQ testing in blood will facilitate ease of testing for CLL patients, but as the COVID-19 pandemic continues, some patients may be unable to or may feel anxious about obtaining a blood draw in a hospital or clinic. To address this, Adaptive has launched a service offering which will enable clonoSEQ patients to safely obtain blood draws in alternate settings. Patients can either access minimal-contact blood collection services at any of the nearly 2,000 LabCorp Patient Service Centers in the U.S., or they can have a blood draw performed by a qualified professional in the comfort of their own homes through Adaptive's collaboration with Phlebotek Solutions, a nationwide provider of mobile phlebotomy services.

"The FDA clearance of clonoSEQ in CLL represents a significant advancement for patients with CLL," said Lance Baldo, Chief Medical Officer of Adaptive Biotechnologies. "We believe this first-time clearance for clonoSEQ in blood will be advantageous for both providers and patients. Given the risks that COVID-19 poses for cancer patients, we are proud to be collaborating with two best-in-class service providers to offer clonoSEQ patients flexible and safe options for blood sample collection outside of a hospital or clinic."

About the clonoSEQ Assay
Prior to CLL, the clonoSEQ Assay was granted De Novo designation and marketing authorization by the FDA for the detection and monitoring of MRD in patients with multiple myeloma (MM) and B-cell acute lymphoblastic leukemia (ALL) using DNA from bone marrow samples. clonoSEQ is the first clinical diagnostic powered by immunosequencing to receive FDA clearance. clonoSEQ 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.

clonoSEQ is a single-site assay performed at Adaptive Biotechnologies. It is also available as a CLIA-validated laboratory developed test (LDT) service for use in other lymphoid cancers. 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 Chronic Lymphocytic Leukemia (CLL)
CLL is a type of cancer in which the bone marrow makes too many lymphocytes (a type of white blood cell). It is one of the most common types of leukemia in adults. The disease often occurs during or after middle age, with the average age of diagnosis at 70 years old. There were more than 20,000 new cases of CLL in the U.S. in 2019 and more than 200,000 people in the U.S. are currently living with CLL. CLL is considered incurable but 5-year and 10-year survival rates are high, such that many people will require additional treatment over time due to the return of cancerous cells.

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 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.

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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