Adaptive Biotechnologies Launches Enhanced clonoSEQ® Assay Reports for Patients with Chronic Lymphocytic Leukemia, Now Featuring IGHV Mutation Status

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Combined ID-IGHV report at time of diagnosis conveniently provides additional prognostic information while also enabling future MRD monitoring in patients

SEATTLE, Sept. 30, 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, announced today the launch of an enhanced version of its clonoSEQ® B-cell Clonality (ID) report, which will now feature the immunoglobulin heavy chain (IgH) – V mutation status for patients with chronic lymphocytic leukemia (CLL). clonoSEQ is the first and only in vitro diagnostic cleared by the U.S. Food and Drug Administration (FDA) to detect and monitor minimal residual disease (MRD) in blood or bone marrow from patients with CLL.

Starting today, all clonoSEQ B-cell Clonality (ID) reports will automatically include IGHV mutation status. IGHV mutation status has been shown to be prognostic of outcomes in CLL, with mutated IGHV genes inferring better outcomes. Guidelines from both the National Comprehensive Cancer Network (NCCN) and the International Workshop on Chronic Lymphocytic Leukemia (iwCLL) recommend testing for the IGHV mutation in the upfront evaluation of newly diagnosed CLL patients. Adding this feature to the clonoSEQ Assay will enable physicians to assess both IGHV status and MRD status with just one assay. Performing clonality (ID) assessment at time of diagnosis is an important step to establish patient-specific sequences to track for subsequent MRD monitoring, and studies have demonstrated that trackable sequences can be found in more than 95% of CLL patients.

“clonoSEQ is a tool I utilize often to assess MRD status in my patients that require time limited therapy for CLL, not only because it is valuable for helping predict potential relapse or survival but also because it informs my patient management,” said Javier Pinilla-Ibarz, MD, PhD, senior member and head of the Lymphoma Program in the Department of Malignant Hematology at Moffit Cancer Center. “Now that patients will also receive their IGHV mutation status through clonoSEQ testing, it will become an even more valuable diagnostic for hematologists to use at the start of patient workups, potentially saving patients both cost and time as there is only one test with two results. With the insights provided by clonoSEQ both through IGHV status at the time of diagnosis and through MRD status during and after treatment, physicians can better personalize treatment regimens in CLL.”

MRD describes the small number of cancer cells that remain in the body during and after treatment. MRD assessment with clonoSEQ 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 detect potential relapse. Evidence generated in CLL clinical trials (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.

“The inherent design of the clonoSEQ Assay enables assessment of a patient’s IGHV mutation status and identification of the trackable sequences we use to monitor their MRD at the same time, so it was a natural evolution for us to make,” said Lance Baldo, MD, Chief Medical Officer of Adaptive Biotechnologies. “We are happy to be able to make the diagnostic journey even simpler by providing physicians and their patients with two clinically valuable CLL tests from a single sample.”

The test for IGHV mutation status is a CLIA-validated lab-developed test (LDT) and an additional feature of the clonoSEQ assay provided at the time of diagnosis. clonoSEQ IGHV mutation status is not FDA cleared or approved. Access to clonoSEQ for CLL patients nationwide is supported by the already-established Medicare coverage of clonoSEQ in CLL.

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. clonoSEQ patients can access minimal-contact blood collection services at any of the nearly 2,000 Labcorp Patient Service Centers in the U.S. or 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. To learn more or place an order, email clinicalservices@adaptivebiotech.com or call (888) 552-8988.

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 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.