Adaptive and Genentech Partner to Use clonoSEQ® Assay to Measure Minimal Residual Disease as a Primary Endpoint in Phase III Study of Chronic Lymphocytic Leukemia Patients

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SEATTLE, Jan. 13, 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 a multi-year, global diagnostic agreement with Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY) to utilize Adaptive's next-generation sequencing (NGS)-based clonoSEQ® Assay to assess minimal residual disease (MRD) status in response to venetoclax in the registrational Phase III CRISTALLO (CO41685) study for the treatment of newly diagnosed people with chronic lymphocytic leukemia (CLL) plus additional future venetoclax studies in CLL. Adaptive and Genentech will partner to incorporate the clonoSEQ Assay to measure MRD status as a primary endpoint in this registrational study. Under the terms of the agreement, Adaptive will receive upfront and sample testing payments to advance the development and potential expedited approval of venetoclax in this setting.

"Adaptive is pleased to partner with Genentech to support the continued clinical development and potential regulatory approval of venetoclax in people with untreated CLL, which expands our work with Genentech in oncology," said Chad Robins, CEO and co-founder of Adaptive Biotechnologies. "This partnership represents another significant step towards the adoption of MRD status as a primary clinical endpoint using clonoSEQ as the preferred MRD test. This is Adaptive's second meaningful partnership which we recently announced that includes the use of clonoSEQ in the development of venetoclax."

Venetoclax is a first-in class small molecule selective B-cell lymphoma-2 (BCL-2) inhibitor being studied in investigational trials for the treatment of people with previously untreated CLL or small lymphocytic lymphoma (SLL). Adaptive and Genentech will evaluate the depth and duration of response to venetoclax and obinutuzumab by using Adaptive's clonoSEQ Assay as a primary endpoint to measure and monitor MRD negativity from peripheral blood in newly diagnosed CLL. clonoSEQ is the only MRD test authorized by the U.S. Food and Drug Administration (FDA) to detect and monitor MRD in multiple myeloma (MM) and B-Cell acute lymphoblastic leukemia (ALL) using DNA from bone marrow samples. clonoSEQ is available as a laboratory develop test (LDT) in CLL using DNA from peripheral blood and bone marrow.

MRD is a measure of the amount of cancer in the body, specifically the very small number of cancer cells that remain during or after treatment. MRD testing can be useful to see if a patient is responding to treatment or if the cancer has come back

About the clonoSEQ Assay

The clonoSEQ Assay was granted de novo designation and marketing authorization by FDA for the detection and monitoring of minimal residual disease (MRD) in patients with multiple myeloma (MM) and B-cell acute lymphoblastic leukemia (ALL) using DNA from bone marrow samples. clonoSEQ is the first and only FDA-authorized *in vitro* diagnostic assay for MRD testing. It is also the first clinical diagnostic powered by immunosequencing to receive FDA clearance. clonoSEQ leverages Adaptive's proprietary immunosequencing 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 detect 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 are strongly associated with MRD levels measured by the clonoSEQ Assay in patients diagnosed with ALL and MM. More than 175 million people in the US now have access to clonoSEQ through Medicare and private payor coverage.

clonoSEQ is a single-site assay performed at Adaptive Biotechnologies. It is also available as a CLIA-regulated 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 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.

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 Adaptive Biotechnologies' partnership with Genentech, 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," "expect," "plan," "believe," "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 the Company files with the Securities and Exchange Commission (the "SEC") 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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