Adaptive Biotechnologies Announces New Translational Collaboration to Measure Minimal Residual Disease with clonoSEQ® Assay Across BeiGene's Lymphoid Malignancy Pipeline

November 7, 2023

- *Data generated by Adaptive's next-generation sequencing-based MRD assay will support the development and commercialization of investigational medicines for hematologic malignancies*

SEATTLE, Nov. 07, 2023 (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 translational collaboration with BeiGene to assess minimal residual disease (MRD) using clonoSEQ® assay technology across the company's pipeline of treatments for patients with lymphoid malignancies.

"Adaptive is pleased to partner with BeiGene to support the clinical development and potential regulatory approval of their investigational therapies in lymphoid malignancies," said Mary Pat Lancelotta, Senior Vice President, BioPharma at Adaptive Biotechnologies. "MRD status has strong prognostic value, and by integrating the measure into clinical studies our partners can more quickly and efficiently evaluate and advance novel therapeutics."

MRD assessment is playing a growing role in clinical trials for lymphoid malignancies by providing an early measure of treatment response and serving as a potential endpoint, which may enable novel therapies to be made available to patients sooner. As the first and only standardized test authorized by the U.S. Food and Drug Administration (FDA) for MRD assessment in bone marrow from patients with multiple myeloma or B-cell acute lymphoblastic leukemia (B-ALL) and blood or bone marrow from patients with chronic lymphocytic leukemia (CLL), Adaptive's clonoSEQ assay technology is the test of choice among drug developers. It has been included in global, label-enabling studies for a multitude of therapies approved over the past several years and is also now widely adopted in the clinic. It is used at all 33 National Comprehensive Cancer Network (NCCN) centers, and as data supporting its clinical utility mount, its use is also growing in the community setting.

This multi-year agreement will cover existing and future programs and adds to Adaptive's growing list of translational collaborations with biopharmaceutical companies. As part of the collaboration, MRD status based on Adaptive's clonoSEQ assay may be used as an endpoint in certain clinical trials to assess the depth and duration of response to BeiGene's investigational medicines in patients with lymphoid malignancies. Adaptive will receive an upfront payment and will be eligible to receive future milestone payments upon achievement of specific regulatory milestones in certain geographies. Specific financial terms of the agreement will not be disclosed.

About the clonoSEQ Assay
The clonoSEQ assay is the first and only FDA-cleared in vitro diagnostic (IVD) test service to detect minimal residual disease (MRD) in bone marrow from patients with multiple myeloma (MM) or B-cell acute lymphoblastic leukemia (B-ALL) and blood or bone marrow from patients with chronic lymphocytic leukemia (CLL). clonoSEQ testing for diffuse large B-cell lymphoma (DLBCL) patients is currently available for clinical use as a laboratory-developed test (LDT) performed at Adaptive's CLIA-certified lab in Seattle, WA. Medicare covers clonoSEQ in these four indications and is aligned with clinical practice guidelines which support assessing MRD at multiple time points throughout therapy to monitor treatment response and help predict patient outcomes.

The clonoSEQ assay leverages Adaptive Biotechnologies' 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, ALL and DLBCL.

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 ("we" or "our") 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. We apply our platform to partner with biopharmaceutical companies, inform drug development, and develop clinical diagnostics across our two business areas: Minimal Residual Disease (MRD) and Immune Medicine. Our commercial products and clinical pipeline enable the diagnosis, monitoring, and treatment of diseases such as cancer, autoimmune disorders, and infectious diseases. Our goal is to develop and commercialize immune-driven clinical products tailored to each individual patient.

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.

ADAPTIVE MEDIA
Erica Jones, Associate Director, Corporate Communications
206-279-2423
media@adaptivebiotech.com

ADAPTIVE INVESTORS
Karina Calzadilla, Vice President, Investor Relations
201-396-1687
investors@adaptivebiotech.com

Source: Adaptive Biotechnologies