Adaptive Biotechnologies Announces Translational Collaboration with Takeda to Measure Minimal Residual Disease with Its clonoSEQ® Assay Across Its Hematologic Malignancy Pipeline

April 12, 2023

Collaboration will cover existing and future programs to aid in the development and commercialization of investigational medicines for hematologic malignancies

SEATTLE, April 12, 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 it has entered into a translational collaboration with Takeda to use its clonoSEQ® Assay to assess minimal residual disease (MRD) to facilitate the development and commercialization of Takeda's pipeline of treatments for patients with lymphoid malignancies.

"We are thrilled to enter into a broad translational collaboration with Takeda incorporating the use of our clonoSEQ Assay technology in clinical trials to support the clinical development of groundbreaking oncological therapies," said Nitin Sood, chief commercial officer, MRD at Adaptive Biotechnologies. "MRD is an important measure of whether novel treatments are inducing effective and durable responses for patients, and its use as an endpoint is rapidly growing."

MRD can be used to assess depth of response and to detect early signs of relapse prior to clinical symptoms. This assessment is performed as a series of tests throughout a patient's cancer journey. The clonoSEQ Assay is the first and only next-generation sequencing-based MRD test authorized by the U.S. Food and Drug Administration (FDA) for MRD assessment in lymphoid malignancies and is highly accurate, sensitive, and standardized compared to other technologies used for disease burden assessment.

"Innovative technology plays a critical role in informing our clinical development plans as we look to bring effective new medicines to patients with hematologic malignancies," said Christine Ward, Head, Precision and Translational Medicine, Oncology Therapeutic Area Unit (OTAU) at Takeda. "This collaboration with Adaptive allows us to further explore the clinical relevance of MRD as we progress our pipeline of investigational medicines."

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 Takeda's investigational medicines in patients with lymphoid malignancies. This multi-year agreement will cover existing and future programs and adds to Adaptive's growing list of translational collaborations with pharmaceutical companies. Adaptive will receive an upfront payment and will be eligible to receive milestone payments upon achievement of specific 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 INVESTORS
Karina Calzadilla, Vice President, Investor Relations
201-396-1687
investors@adaptivebiotech.com

ADAPTIVE MEDIA
Erica Jones, Associate Director, Corporate Communications
845-344-7542
media@adaptivebiotech.com