



Adaptive Biotechnologies Receives New York State CLEP Approval for clonoSEQ to Detect and Monitor Minimal Residual Disease (MRD) in Patients with Certain Blood Cancers

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SEATTLE, July 31, 2019 (GLOBE NEWSWIRE) -- Adaptive Biotechnologies Corporation (Nasdaq:ADPT) ("Adaptive"), a commercial-stage biotechnology company that reads and translates the genetic code of the adaptive immune system with the goal of developing personalized diagnostics and therapeutics to improve patient lives, today announced that the State of New York Clinical Laboratory Evaluation Program (CLEP) has approved the clonoSEQ[®] Assay for the detection and monitoring of minimal residual disease (MRD) in patients with B-cell blood cancers. In addition to CLEP approval, clonoSEQ is also the first test to be authorized by the U.S. Food and Drug Administration (FDA) for MRD assessment in bone marrow samples from patients with B-cell acute lymphoblastic leukemia (ALL) and multiple myeloma.

The CLEP approval makes clonoSEQ testing accessible to patients in New York who have been diagnosed with B-cell cancers, a subset of lymphoid cancers that includes ALL, multiple myeloma, chronic lymphocytic leukemia (CLL) and B-cell non-Hodgkin's lymphoma (NHL). Testing under CLEP may be performed using DNA from bone marrow, blood and archived tissue samples. With this approval, clonoSEQ MRD testing is now available in all 50 states and has a considerable and growing payor footprint (>140MM covered lives to date).

"New York State CLEP approval for clonoSEQ means patients in New York can now work with their cancer care team to incorporate clonoSEQ into their treatment regimen to accurately and reliably assess and monitor their disease over time, using multiple sample types, including blood samples," said, Chad Robins, CEO and co-founder, Adaptive Biotechnologies. "This rigorous approval also supports our ongoing work to expand access to patients and our pursuit of FDA authorization for new indications for clonoSEQ in other lymphoid cancers and sample types."

clonoSEQ has been ordered by clinicians in nearly 300 healthcare systems and institutions, including 27 of the 28 NCCN centers in the United States, and used by more than 30 biopharmaceutical companies in over 120 clinical trials.

"The approval gives patients in New York access to the standardized, FDA-cleared clinical MRD testing that is already being utilized throughout the rest of the country," said Dr. Ajai Chari, Associate Professor of Medicine, Hematology and Medical Oncology at The Tisch Cancer Institute at Mount Sinai, who was a past consultant for the clonoSEQ Assay.

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. clonoSEQ testing is covered by Medicare and an expanding list of private payors in alignment with the FDA label.

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 biotech 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.

Caution Regarding Forward-Looking Statements

This press release may contain forward-looking statements regarding Adaptive's current expectations, including its ability to read and translate the genetic code of the adaptive immune system to develop personalized diagnostics and therapeutics to improve patient lives. Words such as "may," "believe," "expect," "estimate," "predict," or similar expressions, or statements regarding intent, belief, or current expectations are forward-looking statements.

These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, those described more fully in the section captioned "Risk Factors" in the final prospectus related to the public offering filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Adaptive Biotechnologies undertakes no duty to update such information except as required under applicable law.

MEDIA CONTACT:

Beth Keshishian
Director, Corporate Communications
917-912-7195
media@adaptivebiotech.com

INVESTOR CONTACT:

Lynn Lewis or Carrie Mendivil
415-937-5405
investors@adaptivebiotech.com

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