Adaptive Biotechnologies Announces Medicare Coverage of the clonoSEQ® Assay for MRD Testing in Patients with Multiple Myeloma and Acute Lymphoblastic Leukemia at Multiple Timepoints Throughout Treatment and Remission

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SEATTLE, Wa., January 17, 2019 – Adaptive Biotechnologies, an immune driven-medicine company, today announced that Palmetto GBA, a Medicare Administrative Contractor (MAC) and leader in assessing diagnostic technologies through its MolDX program, has established coverage of the clonoSEQ® Assay for Medicare patients with multiple myeloma and B-cell acute lymphoblastic leukemia (ALL). clonoSEQ is the first and only test authorized by the U.S. Food and Drug Administration (FDA) to detect and monitor minimal residual disease (MRD) in myeloma and ALL using DNA from a patient's bone marrow sample. The Medicare coverage for clonoSEQ is aligned with the assay's FDA label and with clinical practice guidelines in myeloma and ALL and includes assessing MRD at multiple time points throughout therapy to monitor treatment response and help predict patient outcomes. The article is effective immediately and enables national coverage of Medicare patients undergoing clonoSEQ testing.

"Availability of sensitive, specific and standardized MRD testing is increasingly crucial to the delivery of optimal patient care in both multiple myeloma and ALL," said Nikhil Munshi, M.D., Director of Basic and Correlative Science at the Jerome Lipper Multiple Myeloma Center at Dana-Farber Cancer Institute. "Medicare coverage for the clonoSEQ Assay will help ensure that eligible patients across the U.S. have access to a highly advanced option for MRD assessment to support more personalized treatment decisions across their course of care."

MRD refers to the remaining number of cancer cells that are present in a patient's body during and after treatment and may eventually lead to recurrence of the disease. Cancer treatment guidelines for myeloma and ALL call for MRD testing to assess disease burden throughout the course of care to help monitor for remission, detect relapse, determine response to treatment and predict patient outcomes. Controlled trials have shown that even the smallest amounts of residual disease significantly predict a patient's long-term clinical outcomes.

"This is great news for patients. The establishment of favorable Medicare coverage for clonoSEQ soon after FDA authorization further demonstrates the clinical relevance of MRD assessment and underscores the benefit that this test delivers in the management of myeloma and ALL patients," said Charles Sang, senior vice president, Adaptive Diagnostics. "clonoSEQ is a highly sensitive and standardized MRD test that enables more cost-effective care by assessing the effectiveness of therapy, monitoring remission and identifying relapse in lymphoid blood cancers, serving as a critical tool to help clinicians decide if a patient should initiate, pause or discontinue a potentially costly treatment regimen."

clonoSEQ testing has been used in 25 of the 28 National Comprehensive Cancer Network (NCCN) centers in the U.S., and Adaptive is working diligently with community practice leaders to increase use in the community setting. As MRD assessment becomes standard practice for patient management across a range of blood cancers, it is essential that clinicians and patients have access to a highly accurate, sensitive and standardized MRD assessment tool. Having satisfied the analytical and clinical validation requirements of the FDA and met the bar for clinical utility required by Medicare, the clonoSEQ Assay addresses this need.

Adaptive continues to work closely with third-party payers to obtain coverage of clonoSEQ for eligible patients in need. With Medicare coverage in place, Adaptive is strongly positioned to expand commercialization of clonoSEQ in 2019. The company is committed to pursuing regulatory approval for additional potential indications for clonoSEQ in other blood cancers and sample types, including blood-based MRD assessment.

The clonoSEQ coverage decision can be found here.

About the clonoSEQ® Assay

The Adaptive Biotechnologies clonoSEQ Assay has been granted De Novo designation by the FDA as an *in vitro* diagnostic (IVD) to detect and monitor minimal residual disease (MRD) in patients with multiple myeloma (MM) and B-cell acute lymphoblastic leukemia (ALL) using DNA from bone marrow samples. It identifies and quantifies specific DNA sequences found in malignant cells, allowing clinicians to monitor patients for changes in disease burden during and after treatment. This robust assay provides sensitive and accurate measurement of residual disease that allows physicians to predict patient outcomes, assess response to therapy over time, monitor patients during remission and detect potential relapse. The clonoSEQ Assay 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.

clonoSEQ was reviewed under the FDA's De Novo premarket review pathway, a regulatory pathway for some low- to moderate-risk novel devices for which there is no legally marketed predicate device.

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 pioneer and leader in immune-driven medicine that aims to improve people's lives by learning from the wisdom of their adaptive immune systems. Adaptive's proprietary immune profiling platform reveals and translates insights from our adaptive immune systems with unprecedented scale and precision. Working with drug developers, clinicians and academic researchers, we are applying these insights to develop products that will transform the way diseases such as cancer, autoimmune conditions, and infectious diseases are diagnosed and treated. For more information, please visit **adaptivebiotech.com**.

CONTACT:
Adaptive Biotechnologies

Beth Keshishian (media)
917-912-7195
media@adaptivebiotech.com