



Adaptive Biotechnologies and Collaborators to Present More than 30 Abstracts on Utility of clonoSEQ® in MRD Testing in Blood Cancer Patients at the 63rd ASH Annual Meeting

December 2, 2021

SEATTLE, Dec. 02, 2021 (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, together with its collaborators will present data from more than 30 abstracts demonstrating the utility of Adaptive's next-generation sequencing (NGS)-based clonoSEQ® Assay in assessing minimal residual disease (MRD) in blood cancer patients at the 63rd Annual Meeting of the American Society of Hematology (ASH), December 11-14.

clonoSEQ is the only U.S. Food and Drug Administration (FDA)-cleared assay for MRD assessment in multiple myeloma (MM), chronic lymphocytic leukemia (CLL) and B-cell acute lymphoblastic leukemia (B-ALL), and is widely available to clinicians and patients across the U.S.

"The data presented at ASH continues to build on evidence supporting the clinical value of serial MRD testing across blood cancers to help hematologists guide patient management, including the decision to stop treatment," said Lance Baldo, MD, Chief Medical Officer of Adaptive Biotechnologies. "In both clinical trial and real-world settings, clonoSEQ has consistently demonstrated how NGS MRD assessment can meaningfully enhance the way patients and their clinicians understand and manage blood cancers."

MRD assessment is a way to directly detect and quantify remaining disease during and after treatment. With clonoSEQ, clinicians can leverage a precise and reliable technique that can detect as little as one cancer cell among a million healthy cells with sufficient input material. This high sensitivity gives clinicians valuable insight into the dynamics of a patient's disease, which can help predict outcomes, assess response, monitor remission, and detect potential relapse.

Data generated using clonoSEQ in its FDA-cleared indications and beyond will be featured in 9 oral presentations and 25 posters at ASH. The data to be presented demonstrate the utility of clonoSEQ for MRD-directed therapy, the value of sustained, deep MRD negativity, and the use of clonoSEQ to identify circulating tumor cells and circulating tumor DNA (ctDNA) in several lymphoma subtypes. The MRD-related data presented at ASH this year demonstrates how MRD-based decision-making is translating directly to improved patient care in blood cancers.

Earlier this month, Palmetto GBAs Molecular Diagnostics Program (MoIDX) finalized a local coverage determination (LCD) which supports Medicare coverage for clonoSEQ to detect and monitor MRD in patients with B-ALL, MM, and CLL. The LCD supports the potential expansion of coverage for additional clonoSEQ indications, providing a clear pathway for Non-Hodgkin Lymphoma (NHL) and other lymphoid cancers.

Key presentation details:

Abstract	Title	Presentation Timing
Oral Presentations		
Chronic Lymphocytic Leukemia		
70	First Prospective Data on Minimal Residual Disease (MRD) Outcomes after Fixed-Duration Ibrutinib Plus Venetoclax (Ibr+Ven) Versus Chlorambucil Plus Obinutuzumab (Clb+O) for First-Line Treatment of CLL in Elderly or Unfit Patients: The Glow Study	Saturday, December 11, 2021: 10:15 AM
640	Longer Term Follow-up of a Multicenter, Phase 2 Study of Ibrutinib Plus Fludarabine, Cyclophosphamide, Rituximab (iFCR) As Initial Therapy for Younger Patients with Chronic Lymphocytic Leukemia	Monday, December 13, 2021: 11:15 AM
Diffuse Large B-Cell Lymphoma		
52	A Prospective Multicenter Study of Minimal Residual Disease Assessment Using a Next-Generation Immunosequencing Assay and CT Monitoring for Surveillance after Frontline Treatment in Diffuse Large B-Cell Lymphoma	Saturday, December 11, 2021: 10:15 AM
B-Cell Acute Lymphoblastic Leukemia		
274	Diagnostic Utility of Multimodal Genomic Profiling for Molecular Classification and MRD Assessment in Adult B-Cell Acute Lymphoblastic Leukemia	Saturday, December 11, 2021: 2:45 PM
Non-Hodgkin Lymphoma		
95	Phase 1/2 Trial of IL7/IL15-Expanded Bispecific LV20.19 CAR T-Cells for Relapsed, Refractory B-Cell Non-Hodgkin Lymphoma	Saturday, December 11, 2021: 10:30 AM
Multiple Myeloma		
79	Daratumumab (DARA) Plus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Patients (Pts) with Transplant-Eligible Newly Diagnosed Multiple Myeloma (NDMM): Updated Analysis of Griffin after 24 Months of Maintenance	Saturday, December 11, 2021: 9:30 AM
481	Daratumumab, Carfilzomib, Lenalidomide and Dexamethasone (Dara-KRd), Autologous Transplantation and MRD Response-Adapted Consolidation and Treatment Cessation. Final Primary Endpoint Analysis of the Master Trial	Sunday, December 12, 2021: 12:00 PM
483	Biologic Basis of the Impact of Autologous Hematopoietic Cell Transplantation in Multiple Myeloma Treated with Quadruplet Therapy	Sunday, December 12, 2021: 12:30 PM

549	Updated Results from CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-Cell Maturation Antigen-Directed Chimeric Antigen Receptor T Cell Therapy, in Patients With Relapsed/Refractory Multiple Myeloma	Sunday, December 12, 2021: 5:00 PM
Poster Presentations		
Acute Lymphoblastic Leukemia		
3485	Performance of Next Generation Sequencing for Minimal Residual Disease Detection for Pediatric Patients with Acute Lymphoblastic Leukemia: Results from the Prospective Clinical Trial DFCI 16-001	Monday, December 13, 2021, 6:00 PM-8:00 PM
Chronic Lymphocytic Leukemia		
1553	Majic: A Phase 3 Prospective, Multicenter, Randomized, Open-Label Trial of Acalabrutinib Plus Venetoclax Versus Venetoclax Plus Obinutuzumab in Previously Untreated Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma	Saturday, December 11, 2021, 5:30 PM-7:30 PM
3753	Zanubrutinib, Obinutuzumab, and Venetoclax in Chronic Lymphocytic Leukemia: Early MRD Kinetics Define a High-Risk Patient Cohort with Delayed Bone Marrow Undetectable MRD and Earlier Post-Treatment MRD Recurrence	Monday, December 13, 2021, 6:00 PM-8:00 PM
3725	Debulking before Initiation of Venetoclax Therapy in Untreated Patients with Chronic Lymphocytic Leukemia: Results from a Phase 3b Study	Monday, December 13, 2021, 6:00 PM-8:00 PM
3754	Fixed Duration Combination Therapy with Ibrutinib (ibr) and Venetoclax (ven) Leads to Deep Responses in Relapsed/Refractory (rel/ref) Chronic Lymphocytic Leukemia (CLL): Results of a Phase 2 Study	Monday, December 13, 2021, 6:00 PM-8:00 PM
Classical Hodgkin Lymphoma		
3491	Prognostic Value of Minimal Residual Disease (MRD) Among Patients with Classical Hodgkin Lymphoma Undergoing Autologous Stem Cell Transplantation	Monday, December 13, 2021, 6:00 PM-8:00 PM
Diffuse Large B-Cell Lymphoma		
1414	High Grade B Cell Lymphoma with MYC and BCL2 and/or BCL6 Rearrangements Treated with DA-EPOCH-R Induction and Nivolumab Consolidation Treatment: Interim Results of the HOVON-152 Phase II Trial	Saturday, December 11, 2021, 5:30 PM-7:30 PM
Follicular Lymphoma		
1328	A Prospective Study of Clonal Evolution in Follicular Lymphoma: Circulating Tumor DNA Correlates with Overall Tumor Burden and Fluctuates over Time without Therapy	Saturday, December 11, 2021, 5:30 PM-7:30 PM
2397	Concurrent Monitoring of Peripheral Blood Circulating Tumor DNA and Circulating Tumor Cells in Relapsed/Refractory Follicular Lymphoma Patients Post Axicabtagene Ciloleucel, a Single Center Experience	Sunday, December 12, 2021, 6:00 PM-8:00 PM
Mantle Cell Lymphoma		
2416	Safety and Efficacy of Acalabrutinib Plus Venetoclax and Rituximab in Patients with Treatment-Naïve (TN) Mantle Cell Lymphoma (MCL)	Sunday, December 12, 2021, 6:00 PM-8:00 PM
3530	Safety and Efficacy of Ibrutinib Maintenance (I-M) Following Frontline Induction in Mantle Cell Lymphoma (MCL) with Sequential Assessment of Changes in NGS-MRD	Monday, December 13, 2021, 6:00 PM-8:00 PM
3537	Phase 1b/2 Study of Vipor (Venetoclax, Ibrutinib, Prednisone, Obinutuzumab, and Lenalidomide) in Relapsed/Refractory and Untreated Mantle Cell Lymphoma: Safety, Efficacy, and Molecular Analysis	Monday, December 13, 2021, 6:00 PM-8:00 PM
Multiple Myeloma		
1625	Retrospective Analysis of Minimal Residual Disease Testing By High Throughput Immunosequencing Versus High Sensitivity Flow Cytometry in Multiple Myeloma	Saturday, December 11, 2021, 5:30 PM-7:30 PM
1648	Progression-Free Survival Outcomes By Response Status for Bortezomib, Melphalan, and Prednisone with or without Daratumumab in Newly Diagnosed Multiple Myeloma: Pooled Subgroup Analysis of Octans and Alcyone	Saturday, December 11, 2021, 5:30 PM-7:30 PM
1739	Baseline Correlates of Complete Response to Idecabtagene Vicleucel (ide-cel, bb2121), a BCMA-Directed CAR T Cell Therapy in Patients with Relapsed and Refractory Multiple Myeloma: Subanalysis of the KarMMa Trial	Saturday, December 11, 2021, 5:30 PM-7:30 PM
2723	Daratumumab Plus Lenalidomide, Bortezomib, and Dexamethasone (D-RVd) in Transplant-Eligible Newly Diagnosed Multiple Myeloma (NDMM) Patients (Pts): A Subgroup Analysis of Griffin	Sunday, December 12, 2021, 6:00 PM-8:00 PM
2759	A Phase 2 Study of Extended Daratumumab, Carfilzomib, Lenalidomide, and Dexamethasone in Newly Diagnosed Multiple Myeloma	Sunday, December 12, 2021, 6:00 PM-8:00 PM
2910	CARTITUDE-2: Efficacy and Safety of Ciltacabtagene Autoleucel, a B-Cell Maturation Antigen (BCMA)-Directed Chimeric Antigen Receptor T-Cell Therapy, in Patients with Multiple Myeloma and Early Relapse after Initial Therapy	Sunday, December 12, 2021, 6:00 PM-8:00 PM
3783	Longitudinal MRD Assessment in Real-World Multiple Myeloma Patients Using Next-Generation Sequencing (clonoSEQ® Assay)	Monday, December 13, 2021, 6:00 PM-8:00 PM
3806	Response Kinetics of Daratumumab-Based Regimens in Patients with Newly Diagnosed or Refractory/Relapsed Multiple Myeloma	Monday, December 13, 2021, 6:00 PM-8:00 PM
3832	Phase 1 Study of CART-Ddbcm, a CAR-T Therapy Utilizing a Novel Synthetic Binding Domain for the Treatment of Subjects with Relapsed and/or Refractory Multiple Myeloma	Monday, December 13, 2021, 6:00 PM-8:00 PM

3866	Efficacy and Safety of Ciltacabtagene Autoleucel (Cilta-cel), a B-Cell Maturation Antigen (BCMA)-Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy, in Lenalidomide-Refractory Patients with Progressive Multiple Myeloma after 1–3 Prior Lines of Therapy: Updated Results from CARTITUDE-2	Monday, December 13, 2021, 6:00 PM-8:00 PM
3938	Efficacy and Safety of Ciltacabtagene Autoleucel in Patients With Relapsed/Refractory Multiple Myeloma: CARTITUDE-1 Subgroup Analysis	Monday, December 13, 2021, 6:00 PM-8:00 PM
3946	Prospective Comparison Study of Prognostic Value of MRD Detected By 8-Color MFC (EuroFlow-NGF) and NGS in Patients with Multiple Myeloma in ASCT Setting	Monday, December 13, 2021, 6:00 PM-8:00 PM
3950	Comparison of MRD Detection in Autografts in Multiple Myeloma between Novel High-Sensitivity Euroflow-NGF and NGS	Monday, December 13, 2021, 6:00 PM-8:00 PM

About the clonoSEQ Assay

The clonoSEQ Assay is the first and only FDA-cleared assay for MRD in chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and B-cell acute lymphoblastic leukemia (ALL). Minimal residual disease (MRD) refers to the small number of cancer cells that can stay in the body during and after treatment. clonoSEQ was initially granted De Novo designation and marketing authorization by the FDA for the detection and monitoring of MRD in patients with MM and ALL using DNA from bone marrow samples. In August 2020, clonoSEQ received additional clearance from the FDA to detect and monitor MRD in blood or bone marrow from patients with CLL.

The clonoSEQ Assay leverages Adaptive's 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 and ALL.

The clonoSEQ Assay is a single-site test performed at Adaptive Biotechnologies. In addition to its FDA-cleared uses, clonoSEQ is also available as a CLIA-validated laboratory developed test (LDT) service for MRD assessment in other lymphoid cancers and sample types, as well as for determination of IGHV mutation status in CLL/SLL patients. 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 three 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 and follow us on www.twitter.com/adaptivebiotech.

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.

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