Adaptive Biotechnologies and Collaborators to Present 28 Studies at ASH 2018 That Support the Use of the clonoSEQ® Assay to Detect and Monitor Minimal Residual Disease in Patients with Blood Cancers

December 1, 2018

New data demonstrate increasing use of MRD in multiple myeloma and acute lymphoblastic leukemia clinical trials to assess response to therapy

Studies show ability of clonoSEQ to detect MRD in blood samples

Seattle, WA, November 30, 2018 – Adaptive Biotechnologies and its collaborators will present 28 studies, including a late-breaker presentation, at the 60th American Society of Hematology (ASH) Annual Meeting & Exposition in San Diego, December 1-4, 2018. The data presented at ASH builds on the recent FDA clearance of the clonoSEQ® Assay to detect and monitor minimal residual disease (MRD) in patients with multiple myeloma or B-cell acute lymphoblastic leukemia (ALL), using DNA from a patient's bone marrow sample.

Among the 28 clonoSEQ studies at ASH, new research supports expanded use in myeloma and ALL, efficacy in other blood cancers like chronic lymphocytic leukemia (CLL) and Non-Hodgkin's Lymphoma (NHL), and ability to detect MRD in blood-based samples. New data generated using clonoSEQ will be presented that demonstrate the value of a highly sensitive, standardized next-generation sequencing MRD test to determine early response to treatment and predict potential relapse in myeloma and ALL patients. Data will also be presented that look at the sensitivity of clonoSEQ and other technologies to assess MRD.

"This year has been a landmark year for minimal residual disease. It's one of the first new endpoints we've seen in hematology clinical trials since progression-free survival," said Chad Robins, chief executive officer and co-founder of Adaptive Biotechnologies. "The volume and the quality of MRD data being presented at ASH establish that MRD has firmly taken root as a clinical trial endpoint and biomarker that can help predict patient outcomes. With greater reliance on MRD in clinical trials, as well as a growing focus on monitoring MRD to inform patient care, having access to a highly sensitive, standardized test like clonoSEQ is paramount."

clonoSEQ, the first clinical application of Adaptive's pioneering immune profiling platform, will be featured in a late-breaker presentation, 12 oral presentations and 15 posters. Data on approved, investigational and research uses will be presented across a range of cancers – 14 multiple myeloma, 4 ALL, 4 CLL, 4 mantle cell lymphoma, 1 diffuse large B-cell lymphoma, and 1 Hodgkin's lymphoma.

Key highlights include:

Abstract	Title	Date, Time, Location
Multiple myeloma and ALL		
Abstract #LBA-2, Late-Breaker Presentation	LBA-2: Phase 3 Randomized Study of Daratumumab Plus Lenalidomide and Dexamethasone (D-Rd) Versus Lenalidomide and Dexamethasone (Rd) in Patients with Newly Diagnosed Multiple Myeloma (NDMM) Ineligible for Transplant (MAIA)	Tuesday, December 4, 7:30 AM PT, Hall AB, San Diego Convention Center
Abstract #156, Oral Presentation	One-Year Update of a Phase 3 Randomized Study of Daratumumab Plus Bortezomib, Melphalan, and Prednisone (D-VMP) Versus Bortezomib, Melphalan, and Prednisone (VMP) in Patients (Pts) with Transplant-Ineligible Newly Diagnosed Multiple Myeloma (NDMM): Alcyone	Saturday, December 1, 1:15 PM PT, Grand Ballroom 7, Marriott Marquis San Diego Marina
Abstract #123, Oral Presentation	Ixazomib-Lenalidomide-Dexamethasone (IRd) Consolidation Following Autologous Stem Cell Transplantation in Patients with Newly Diagnosed Multiple Myeloma: A Large Multi-Center Phase II Trial	Saturday, December 1, 10:00 AM PT, Grand Hall C, Manchester Grand Hyatt San Diego
Abstract #281, Oral Presentation	Multivariable Modeling of Disease and Treatment Characteristics of Adults with B-ALL in MRD-Negative CR after CD19 CAR-T Cells Identifies Factors Impacting Disease-Free Survival	Sunday, December 2, 8:30 AM PT, Ballroom 20D, San Diego Convention Center
Abstract #1551, Poster Presentation	Molecular Detection of Minimal Residual Disease Precedes Morphological Relapse and Could be Used to Identify Relapse in Pediatric and Young Adult B-Cell Acute Lymphoblastic Leukemia Patients Treated with Tisagenlecleucel	Saturday, December 1, 6:15 PM PT, Hall GH, San Diego Convention Center
Abstract #3272, Poster Presentation	Evaluation of Sustained Minimal Residual Disease (MRD) Negativity in Relapsed/Refractory Multiple Myeloma (RRMM) Patients (Pts) Treated with Daratumumab in Combination with Lenalidomide Plus Dexamethasone (D-Rd) or Bortezomib Plus Dexamethasone (D-Vd): Analysis of Pollux and Castor	Sunday, December 2, 6:00 PM PT, Hall GH, San Diego Convention Center
Blood-based MRD Monitoring		

Abstract #147, Oral Presentation	Circulating Tumor DNA Dynamics during Therapy Predict Outcomes in Mantle Cell Lymphoma	Saturday, December 1, 12:30 PM PT, Pacific Ballroom 20, Marriott Marquis San Diego Marina
Abstract #3137, Poster Presentation	Undetectable-Minimal Residual Disease (U-MRD6) (10-6 sensitivity) Is Associated with Best Progression-Free Survival for Patients Who Achieve Bone Marrow Undetectable MRD4 (10-4 sensitivity) with First-Line FCR	Sunday, December 2, 6:00 PM PT, Hall GH, San Diego Convention Center

About Minimal Residual Disease
Minimal residual disease (MRD), also referred to as measurable residual disease, refers to cancer cells that remain in the body after treatment for patients with lymphoid cancers. These cells can be present at levels undetectable by traditional morphologic methods, microscopic examination of blood, or a bone marrow or a lymph node biopsy.

MRD is used by physicians to detect and monitor disease burden in patients and to inform their treatment decisions. Clinical practice guidelines recommend assessing MRD at multiple time points during treatment and maintenance in MM and ALL, and guidelines for both diseases include NGS as a recommended testing method. The prognostic value of MRD assessment has been demonstrated in multiple lymphoid cancers. Controlled trials have shown that even small amounts of disease are profoundly significant for predicting a patient's long-term clinical outcomes. Therefore, highly sensitive, standardized molecular technologies are needed for reliable detection of MRD.

Measurement of MRD is currently being evaluated as a way to measure efficacy in drug trials, with the potential to expedite the approval of emerging therapies.

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 the pioneer and leader in combining next-generation sequencing (NGS) and expert bioinformatics to profile T-cell and B-cell receptors. Adaptive is bringing the accuracy and sensitivity of its immunosequencing platform to researchers and clinicians around the world to drive groundbreaking research in cancer and other immune-mediated diseases. Adaptive also translates immunosequencing discoveries into clinical diagnostics and therapeutic development to improve patient care. For more information, please visit **adaptivebiotech.com**.

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