Adaptive Biotechnologies Enters Partnership with Illumina to Develop Distributable IVD Test Kits for clonoSEQ and immunoSEQ Dx

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Partnership Will Enable Physicians to Order Clinical Immunodiagnostic Testing that Can Be Performed in Local Laboratories

SEATTLE, Wash., Sept. 24, 2019 (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 a partnership with Illumina, Inc. (Nasdaq: ILMN) to develop in-vitro diagnostic (IVD) test kits for Adaptive’s current and future portfolio of next-generation sequencing (NGS)-based immunodiagnostics.

The test kits under development would expand the availability of Adaptive’s clonoSEQ ® Assay for assessing and monitoring minimal residual disease (MRD) for the management of patients with certain blood cancers and immunoSEQ Dx ® Assay for pipeline applications. Clinicians currently order clonoSEQ to monitor MRD as a test performed at Adaptive’s lab in Seattle. The planned IVD test kits will make it possible for hospitals and health systems to run Adaptive’s clonoSEQ and immunoSEQ Dx assays in their local laboratories across the United States.

“We are proud to partner with Illumina to deliver on our promise to develop distributable kits for our novel immunodiagnostics to reach more patients,” said Chad Robins, chief executive officer and co-founder of Adaptive Biotechnologies. “These IVD test kits will further validate Adaptive as a valued partner for standardized MRD monitoring and immune profiling solutions from research to the clinic.”

Adaptive’s immune medicine platform is uniquely suited for the development of standardized IVD test kits. Under the non-exclusive agreement, Adaptive will develop the clonoSEQ and immunoSEQ Dx IVD test kits to run on Illumina’s NextSeq™ 550Dx system Adaptive will be responsible for obtaining necessary regulatory approvals for each IVD test kit and for their subsequent commercialization.

“By making Adaptive’s clonoSEQ more accessible to patients, we are ensuring health care providers have access to a valuable part of a growing genomics ecosystem. Partnerships that bring exceptional clinical content to customers and patients represent an exciting opportunity in clinical genomics,” said Dr. Phil Febbo, Chief Medical Officer of Illumina. “We are committed to unlocking the power of the genome through our work with Adaptive which will expand access to genomic-based testing in order to improve patient outcomes.”

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 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 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.

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 Adaptive Biotechnologies’ partnership with Illumina, 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,” “expect,” “plan,” “believe,” “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 the Company files with the Securities and Exchange Commission (the “SEC”) 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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