Adaptive Announces IVDR Certification for clonoSEQ® in European Union

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clonoSEQ is the first IVDR-certified test to detect minimal residual disease in patients with lymphoid malignancies

SEATTLE, Aug. 29, 2024 (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 that clonoSEQ® has received In Vitro Diagnostic Regulation (IVDR) 2017/746 Class C certification in the European Union (EU).

The medical diagnostics field has experienced significant technological advancement in recent years, leading the EU to replace its previous regulatory framework, the In Vitro Diagnostics Directive (IVDD), with a more stringent set of standards for quality and safety, known as IVDR. Adaptive worked with EU notified body BSI to complete the certification process and transition the company's IVDD CE-marked product, the clonoSEQ Assay B-Cell Reagent Set, to this new regulation. clonoSEQ is now the first and only test to receive IVDR certification for the detection of minimal residual disease (MRD) in lymphoid malignancies. clonoSEQ's intended use under IVDR is broad in scope, allowing for assessment of MRD status and changes in disease burden during and after treatment in patients diagnosed with B-cell malignancies.

"IVDR certification further distinguishes clonoSEQ and underscores Adaptive's commitment to providing best-in-class MRD testing for European healthcare professionals, patients and clinical trial sponsors," said Susan Bobulsky, chief commercial officer, MRD, Adaptive Biotechnologies. "We're pleased to be the first CE-marked MRD test to meet this regulatory standard, to enable European labs to offer IVDR-compliant clonoSEQ MRD testing locally, and to offer IVDR-compliant testing in clinical trials to support biopharmaceutical clients."

As MRD testing becomes increasingly adopted in patient care, clonoSEQ provides a powerful and dynamic way to measure risk status for patients with lymphoid malignancies and yields real-time insights into disease progression that can help oncologists provide a more personalized treatment approach.

"MRD assessment is an incredibly valuable tool for providing individualized treatment to improve standards of care for blood cancer patients," said Mohamad Mohty, M.D., Ph.D., professor of hematology and head of the Hematology and Cellular Therapy Department at the Saint-Antoine Hospital and Sorbonne University in Paris, France. "With the adoption of the more rigorous standards established by IVDR, when utilizing clonoSEQ, we can trust that we are using a fully validated assay following the strictest standards for safety, quality and performance in our practice."

In addition to clinical use, clonoSEQ is the test of choice for MRD assessment among drug developers performing clinical research in hematologic malignancies. The assay has been included in global, label-enabling studies for a multitude of therapies approved by the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) over the past several years. IVDR certification allows Adaptive to meet the clinical trial regulations for testing EU subjects' samples, and sponsors can seamlessly send clinical trial subjects' samples from the EU to Adaptive's Seattle, Washington laboratory.

"clonoSEQ is a highly validated prognostic test that can support therapeutic decision-making in the daily management of patients as well as potentially expedite clinical trials to support drug development," said Carolina Terragna, Ph.D., executive biologist, Laboratory of Molecular Biology, University Hospital of Bologna IRCCS. "The IVDR approval ensures continued access in Europe to the most reliable way to measure treatment efficacy in lymphoid malignancies."

clonoSEQ is well-established as a leading tool in blood cancer MRD assessment, supported by more than 150 peer-reviewed publications and used clinically by more than 3,700 clinicians over the past year. Furthermore, clonoSEQ MRD is currently being utilized in more than 160 active biopharma-sponsored trials. clonoSEQ is available locally in the EU to oncologists through technology transfer partnerships with major academic laboratories. clonoSEQ testing can currently be performed in France by Centre Hospitalier Universitaire (CHU) Toulouse, in Italy by Hospital of Bologna, in Spain by Hospital 12 du Octubre, and in Germany by HPH laboratory. Additional technology transfer partnerships are expected to launch in the EU and surrounding markets later in 2024. For additional information, contact dxsupport@adaptivebiotech.com.

About clonoSEQ
clonoSEQ is the first and only FDA-cleared in vitro diagnostic (IVD) test service to detect minimal residual disease (MRD) in bone marrow from patients with multiple myeloma (MM) or B-cell acute lymphoblastic leukemia (B-ALL) and blood or bone marrow from patients with chronic lymphocytic leukemia (CLL). clonoSEQ testing for diffuse large B-cell lymphoma (DLBCL) patients is currently available for clinical use as a laboratory-developed test (LDT) performed at Adaptive's CLIA-certified lab in Seattle, WA. clonoSEQ is CE-marked under IVDR in the EU. For the approved intended use in the EU under IVDR, please refer to the instructions for use, available on request.

clonoSEQ leverages Adaptive Biotechnologies' 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 treatment, inform changes in therapy, monitor disease burden over time, and detect potential relapse early. 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, ALL and DLBCL.

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 ("we" or "our") 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. We apply our platform to partner with biopharmaceutical companies, inform drug development, and develop clinical diagnostics across our two business areas: Minimal Residual Disease (MRD) and Immune Medicine. Our commercial products and clinical pipeline enable the diagnosis, monitoring, and treatment of diseases such as cancer, autoimmune disorders, and infectious diseases. Our goal is to develop and commercialize immune-driven clinical products tailored to each individual patient.

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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