Adaptive Biotechnologies Presents New Data During IDWeek Demonstrating the Capability of Its Immune Medicine Platform to Distinguish Between SARS-CoV-2 Infection and Vaccine Response and Detect Lyme Disease

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Real-world data show T-Detect™ COVID can detect prior SARS-CoV-2 infection nearly 12 months after initial diagnosis in some patients

New research demonstrates T-cell testing using T-cell receptor (TCR) repertoire characterization can distinguish natural SARS-CoV-2 infection from COVID-19 vaccine response

Late-breaking data show TCR repertoire characterization is nearly two times more sensitive than the standard two-tiered testing (STTT) at identifying Lyme disease

SEATTLE, Oct. 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, is presenting new data from three studies demonstrating the potential clinical utility of T-cell testing using T-cell receptor (TCR) repertoire characterization for infectious diseases during IDWeek 2021, which is being held virtually. Data demonstrate potential advantages over conventional testing methods in SARS-CoV-2 and Lyme disease.

In SARS-CoV-2, new real-world data demonstrate that T-Detect™ COVID can detect prior infection nearly 12 months after diagnosis in some patients. Additionally, T-cell testing can be used to distinguish natural SARS-CoV-2 infection from COVID-19 vaccine response, an important advantage over antibody tests. In Lyme disease, a late-breaking abstract showed TCR repertoire characterization to be nearly two times more sensitive than standard two-tiered testing (STTT) at identifying individuals with early disease.

“Our data presented at IDWeek this year reflects the growing evidence that Adaptive’s immune medicine platform can be applied to develop tests that could potentially provide valuable clinical information for patients,” said Lance Baldo M.D., Chief Medical Officer, Adaptive Biotechnologies. “These data play a critical role in advancing the T-Detect pipeline and Adaptive’s vision to leverage data from the human immune system to diagnose and treat disease.”

T cells are the adaptive immune system’s first responders to many different diseases and play a critical role in the clearance of pathogens as well as regulating both cellular and antibody-mediated immunity. Given that T cells are highly specific for their disease target and circulate freely in the blood, they are an easy and desirable target for assessing exposure and potential immunity to specific pathogens. A T-cell response can be measured within days from initial pathogen exposure and can persist for years even when antibodies become undetectable. T-cell testing using TCR repertoire characterization can provide a consistent and trackable measure of the immune response to many diseases, such as SARS-CoV-2 and Lyme disease.

SARS-CoV-2 Oral Presentations

Data presented at IDWeek suggest that T-cell testing can provide important insights into the SARS-CoV-2 immune response, with potential implications for clinical management, risk stratification, surveillance, assessing protective immunity, and understanding long-term effects. The first study looked at the clinical performance of T-Detect COVID, the first T-cell test available in the U.S. to confirm recent or prior SARS-CoV-2 infection from whole blood samples. Results from this analysis and a real-world evidence data set confirm and extend previously published findings regarding the durability of the detectable T-cell response, from 5 months after an initial positive Reverse Transcription (RT)-Polymerase Chain Reaction (PCR) test result to nearly 12 months in a small number of evaluable patients.

Additionally, another study demonstrated that TCR repertoire characterization produced a quantitative picture of the T-cell response to SARS-CoV-2 and demonstrated the ability to distinguish a vaccine response from a natural infection based on the relative absence of T-cell receptors targeting non-spike antigens in vaccinated individuals.

These presentations are available on demand for the duration of the conference.

Lyme Disease Late Breaker Presentation

Adaptive also presented data at the meeting from a study evaluating TCR repertoire characterization in patients with early Lyme disease, within 30 days from symptom onset. These results demonstrate that T-cell testing using TCR repertoire characterization is nearly two times more sensitive compared to STTT in early Lyme disease and three times more sensitive in the first few days of symptom onset.

“These results demonstrate transformative potential of combining biology with cloud-scale machine learning to unlock the information encoded by our immune systems,” said Jonathan Carlson, General Manager of Immunomics at Microsoft. “T-Detect COVID is an important proof-of-concept for the clinical and scientific utility of T-cell testing, and we are thrilled to show the feasibility of the underlying technology in another infectious disease.”

Summaries of Key Data Presented at IDWeek:

Clinical Validation and Performance of a Novel T-Cell Immunosequencing Assay to Identify Past SARS-CoV-2 Infection

- This clinical validation study looked at three different cohorts of over 500 patient samples from distinct study arms collected nationwide over two years, including:

    - A retrospective arm with remnant clinical samples confirmed for SARS-CoV-2 infection by RT-PCR and samples presumed negative;
    - A second retrospective arm of confirmed SARS-CoV-2 residual samples from a prior study; and
    - A prospective arm that collected samples from participants with symptoms compatible with SARS-CoV-2 and either positive or negative test results by RT-PCR and antibody test
- Samples from these study arms were used to evaluate clinical agreement of T-Detect COVID to determine positive percent agreement (PPA) and negative percent agreement (NPA).
- Results demonstrate that T-Detect COVID exhibits high clinical performance in identifying recent or prior SARS-CoV-2 infection from whole blood samples.
- Clinical validation of T-Detect COVID shows it exhibits high PPA with SARS-CoV-2 RT-PCR testing, high NPA in SARS-CoV-2–negative samples, and no evidence of cross-reactivity with other viruses or pathogens.
- The sensitivity of T-Detect COVID is equivalent to or greater than serology testing in RT-PCR-confirmed SARS-CoV-2 cases.
- Real-world data show that T-Detect COVID demonstrates 100% PPA in individuals with RT-PCR–confirmed SARS-CoV-2.
- Real-world data also show that T-Detect COVID detected positive SARS-CoV-2 samples up to nearly 12 months after initial RT-PCR in a small number of individuals.

Magnitude and Dynamics of the T-Cell Response to SARS-CoV-2 Infection and Vaccination

- TCR repertoire characterization from whole blood reliably measures the adaptive immune response to SARS-CoV-2.
- The T-cell response can be detected soon after viral antigenic exposure (before antibodies are typically detectable) and at later time points.
- TCR repertoire characterization demonstrated an 86.4% sensitivity in determining a natural infection and can distinguish this from a vaccine-mediated immune response with greater than 99% specificity.
- TCR repertoire characterization has potential applications in clinical diagnostics, vaccine development, and vaccine monitoring.

Immunosequencing of the TCR repertoire reveals signatures specific for diagnosis and characterization of early Lyme disease

- In a validation cohort of over 200 individuals with early Lyme disease, TCR repertoire sequencing demonstrated a near doubling in sensitivity for identifying disease compared to STTT (56% vs. 30%) in patients tested within 30 days of symptom onset (2/3 of patients were tested within <8 days of symptom onset), with the sensitivity over STTT being most significant in the four days following the onset of symptoms (44% vs 14%).
- TCR repertoire sequencing was approximately 99% specific in an independent set of control samples that had all tested STTT-negative.
- 37% of early Lyme cases that initially tested STTT negative were identified.
- Additionally, the relative abundance of T-cell signatures was found to correlate with disease severity markers, such as abnormal liver function tests, disseminated rashes, and several other Lyme disease-associated symptoms.

About T Detect™
T-Detect™ is a highly sensitive and specific test under development to detect multiple diseases, translating the natural diagnostic capability of T cells into clinical practice. In 2018, Adaptive and Microsoft partnered to build a map of the immune system called the TCR-Antigen Map. This approach uses immunosequencing, proprietary computational modeling, and machine learning to map T-cell receptor sequences to disease-associated antigens for infectious diseases, autoimmune disorders and cancer. From a simple blood draw, T-Detect will leverage the map to enable early disease diagnosis, disease monitoring, and critical insights into immunity for patients. T-Detect COVID is the first clinical test launched from this collaboration and the first commercially available T-cell test designed to detect recent or prior SARS-CoV-2 infections. T-Detect COVID is not FDA-cleared or approved, it has received an EUA from the FDA and is available for prescription use only.

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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