



Adaptive Biotechnologies Announces FDA Emergency Use Authorization for T-Detect™ COVID to Confirm Recent or Prior COVID-19 Infection

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First and only clinical T cell-based test for patients to detect the unique T-cell signature specific to SARS-CoV-2, the virus that causes COVID-19

T-Detect COVID correctly confirmed recent or prior COVID-19 infections 97.1% of the time from date of RT-PCR diagnosis with 100% specificity

SEATTLE, March 05, 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, today announced that the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for T-Detect™ COVID to confirm recent or prior COVID-19 infection. This first-in-class T cell- based test is the first indication resulting from Adaptive's TCR-Antigen Map collaboration with Microsoft (Nasdaq: MSFT).

"We are proud to receive FDA Emergency Use Authorization for T-Detect COVID, the first indication in an entirely new class of tests that use T cells in the blood to detect disease. People who have been unsure about a prior infection will now have another way to know if they had the virus," said Chad Robins, chief executive officer of Adaptive Biotechnologies. "The authorization of T-Detect COVID represents a true breakthrough for patients and a pivotal milestone for the diagnostic testing paradigm. We have proven that it is possible to read how T cells detect disease in the blood, and this is just the beginning of a pipeline of tests for many other indications."

EUA was based on a clinical validation study showing that T-Detect COVID demonstrated sensitivity of 97.1% from date of diagnosis using RT-PCR. Sensitivity is the ability of the test to correctly identify a positive case (true positive). T-Detect COVID also showed a specificity of 100%. Specificity is the ability of the test to identify a negative case (true negative).

"This is the first commercially available T-cell test that confirms recent or prior SARS-CoV-2 infections in people. T-Detect is accurate and what I find especially remarkable is how rapidly it was developed. Going from the lab to real-world human impact in a matter of months demonstrates the true value of our collaboration and the power of merging biology with cloud-scale machine learning technology," said Peter Lee, corporate vice president, Research & Incubations, Microsoft. "We are hopeful that this technology will have a meaningful impact not only in the global fight against COVID-19, but in many other disease areas in the future."

The FDA provides an EUA for medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives.

About the T cell

T cells are the adaptive immune system's first responders to detect any virus. They quickly multiply and circulate in the blood to attack the virus, often before symptoms appear. Among many other jobs, T cells also recruit B cells to produce antibodies after about a week or two to potentially provide immunity against future infection. T cells contain a treasure trove of information that could provide one consistent and trackable measure of the immune response to COVID-19 from initial exposure through viral clearance.

T cells can "remember" prior infections and kill pathogens if they reappear. Research shows that antibodies to SARS-CoV-2 decline over time. T cells hold important clues to immunity and correlates of protection and need to be studied to assess how long patients remain resistant to reinfection. Given T cells circulate freely in the blood, they are an easy and thus a desirable target for assessing SARS-CoV-2 exposure and potentially immunity.

About T-Detect™

T-Detect™ is a highly sensitive and specific diagnostic test under development for 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 provide an immunostatus for an individual, enabling early disease diagnosis, disease monitoring, and critical insights into immunity. 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 an EUA authorized test that 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, including forward-looking statements contained in this press release or elsewhere related to T-Detect COVID and its ability to detect recent or prior COVID-19 infection, either in its current form or with respect to future mutations of the virus, as well as the potential application of T-Detect to additional disease states.

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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