Nature Publishes New Research from Vir Biotechnology Demonstrating the Capacity of Enhanced Monoclonal Antibodies to Induce Protective Adaptive Immunity to Viral Infection

October 9, 2020

- Data demonstrate potential to enhance effector function of monoclonal antibodies and induce a protective T-cell or “vaccinal” response
- Therapeutic approach previously applied to treatment of oncologic diseases may now have broader implications across a range of infectious diseases

SAN FRANCISCO, Oct. 09, 2020 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced the publication of preclinical research in an influenza animal model highlighting a new mechanism for enhancing the efficacy of monoclonal antibodies to treat viral infection and induce a protective response. Data demonstrate that selective engagement of an activating Fc receptor on dendritic cells by antiviral monoclonal antibodies induced protective $CD8^+$ T cell adaptive responses. The paper, entitled “Fc-optimized antibodies elicit CD8 immunity to viral respiratory infection,” was published in the October 8, 2020 online edition of *Nature*.

“In the past several years, we've gained a better understanding of how integral Fc mediated effector functions of monoclonal antibodies are for their therapeutic efficacy in pre-clinical models of neoplastic, infectious and inflammatory diseases,” said Jeffrey V. Ravetch, M.D., Ph.D., study senior author and Theresa and Eugene M. Lang Professor and Head of the Leonard Wagner Laboratory of Molecular Genetics and Immunology at The Rockefeller University. “These approaches have been successfully applied to anti-tumor therapeutics and have resulted in improved clinical outcomes in a variety of oncologic diseases. Our present studies have uncovered a significant new mechanism by which antibodies, through their Fc region, can not only engage innate immune responses but activate adaptive T cell responses, thereby stimulating protective anti-viral immunity in these models.”

The research published in *Nature* focuses on the role of the Fc domain of monoclonal antibodies, regions with the capacity to bind to other immune cells through a family of receptors (the Fc receptors). By engineering antibodies with modified Fc domains to enhance binding to specific Fc receptors on innate immune cells, investigators observed an enhanced protective immune response. Certain modifications (GAALIE variants) were associated with activation of dendritic cells, as well as antiviral effector T-cells, indicating induction of the adaptive arm of the immune system, which is responsible for long-term immunity. Based on this research, monoclonal antibodies programmed with improved effector function represent a potential new approach in the design of therapeutic antibodies for both the prevention and treatment of infectious diseases.

“By observing and learning from our body’s powerful natural defenses, we have discovered how to maximize the capacity of antibodies through the amplification of key characteristics that may enable more effective treatments for viral diseases,” said Herbert “Skip” Virgin, M.D., Ph.D., study co-author and executive vice president, research, and chief scientific officer of Vir. “These data may have significant implications across a wide range of infectious diseases, and we look forward to exploring the vaccinal potential of the GAALIE-engineered antibodies we are advancing through clinical development – VIR-3434 for chronic hepatitis B and VIR-7832 for SARS-CoV-2.”

The preclinical study was conducted by Dr. Ravetch and Stylianos Bournazos, Ph.D., of the Laboratory of Molecular Genetics and Immunology at The Rockefeller University, in collaboration with Dr. Virgin and Davide Corti, Ph.D., senior vice president of antibody research at Vir’s subsidiary Humabs BioMed SA.

“This type of exceptional collaborative partnership between cutting-edge science and clinical application has the potential to significantly improve our ability to address infectious diseases,” stated Dr. Virgin.

Vir is currently evaluating several monoclonal antibodies that have been Fc engineered to include the XX2 “vaccinal mutation” (or GAALIE variant) for which Vir has licensed exclusive rights for all infectious diseases.

About VIR-3434
VIR-3434 is a subcutaneously administered HBV-neutralizing monoclonal antibody designed to block entry of all 10 genotypes of HBV into hepatocytes and also to reduce the level of virions and subviral particles in the blood. VIR-3434 has been engineered to have an extended half-life as well as to potentially function as a T cell vaccine against HBV in infected patients.

About VIR-7832
VIR-7832 is a monoclonal antibody that has shown the ability to neutralize SARS-CoV-2 live virus in vitro. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (also known as SARS), indicating that the epitope is highly conserved, which may make it more difficult for escape mutants to develop. VIR-7832 has been engineered with the potential to enhance lung bioavailability, have an extended half-life, and function as a therapeutic and/or prophylactic T cell vaccine. VIR-7832 is being developed by Vir and its partner GlaxoSmithKline plc (LSE/NYSE: GSK) as part of their broader collaboration to research and develop solutions for coronaviruses, including SARS-CoV-2.

About Vir Biotechnology
Vir Biotechnology is a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Vir has assembled four technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current development pipeline consists of product candidates targeting hepatitis B virus, influenza A, SARS-CoV-2, human immunodeficiency virus and tuberculosis. For more information, please visit www.vir.bio.

Vir Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "potential," "may," "will," "could," "expect," "plan," "anticipate," "believe," "estimate," "goal," "intend," "candidate," "continuing," "developing" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Vir's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding the ability of enhanced Fc mediated effector functions in enhancing the efficacy of monoclonal antibodies to treat viral infections and inducing a protective response in animal models, using an oncological therapeutic approach and enhanced effector function in the treatment of infectious diseases, the vaccinal potential of specifically engineered antibodies in the treatment of chronic hepatitis B and SARS-CoV-2, and statements around the company's plans to explore the vaccinal potential of engineered antibodies as it advances through clinical development of VIR-3434 for the treatment of chronic hepatitis B and VIR-7832 for SARS-CoV-2. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, challenges in treating chronic hepatitis B and neutralizing SARS-CoV-2, difficulty in collaborating with other companies or government agencies, and challenges in accessing manufacturing capacity. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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Source: Vir Biotechnology, Inc.