Vir Biotechnology and GSK Announce NHS-Supported AGILE Study to Evaluate VIR-7832 in the Early Treatment of COVID-19

January 12, 2021

- Second monoclonal antibody from Vir-GSK collaboration to be investigated as a potential COVID-19 treatment
- Preclinical data suggest VIR-7832 has two distinguishing properties: enhanced ability to clear infected cells and potential to enhance virus-specific T cell function, which could help treat and/or prevent COVID-19 infection
- Trial targeted to begin in 1Q:2021 at multiple sites across the UK

SAN FRANCISCO and LONDON, Jan. 12, 2021 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) and GlaxoSmithKline plc (LSE/NYSE: GSK) today announced an agreement with the U.K.-based AGILE initiative to evaluate VIR-7832 in patients with mild to moderate COVID-19 in a Phase 1b/2a clinical trial. VIR-7832 is a neutralizing COVID-19 antibody that preclinical data suggests has two distinguishing properties: an enhanced ability to clear infected cells and the potential to enhance virus-specific T-cell function, which could help treat and/or prevent COVID-19 infection.

The AGILE trial platform, which will be the first to test VIR-7832 in humans, uses adaptable protocols and statistical models to enable the evaluation of candidate medicines for COVID-19 treatment. The initiative is a collaboration between the University of Liverpool, Liverpool School of Tropical Medicine, Liverpool University Hospitals NHS Foundation Trust, University of Southampton and Lancaster University and coordinated by the National Institute for Health Research Southampton Clinical Trials Unit across the UK Clinical Research Facility Network. The trial is due to begin in the first quarter of 2021.

George Scangos, Ph.D., chief executive officer of Vir, said: “We are pleased to have the support of the NHS behind our efforts to evaluate and advance VIR-7832 for the treatment and potential prevention of COVID-19. This study will be critical to our efforts as we work to understand whether the modifications we have made to this monoclonal antibody increase its potency and stimulate a T cell response to not only provide therapeutic benefits but also potentially confer a vaccine-like effect that could be applicable to prophylaxis.”

Dr. Hal Barron, chief scientific officer and president R&D, GSK, said: “While vaccine development has been very successful, current infection and hospitalization rates show that multiple vaccines and therapeutic options will be needed to combat and ultimately end this pandemic. We are grateful to everyone involved in the AGILE study for supporting this important research and expect initial results from the study to provide important insights into the use of VIR-7832 early in the course of infection with SARS-CoV-2.”

VIR-7832 is set to become the second monoclonal antibody from the Vir-GSK collaboration to be investigated as a potential COVID-19 treatment. The first antibody, VIR-7831, is currently being investigated in two global phase 3 studies; for the early treatment of COVID-19 in patients who are at high risk of hospitalization, and for the treatment of hospitalized patients with COVID-19.

Phase 1b/2a AGILE Study Design
AGILE is a randomized, controlled, multi-center, seamless, adaptive Phase 1b/2a platform for the rapid evaluation of candidates of COVID-19 treatment in hospitalized patients and also in the community with early disease. The AGILE platform will assess VIR-7832 and VIR-7831 in adult outpatients with mild to moderate COVID-19 infection. The dose-escalation Phase 1b part of the study will evaluate the safety and tolerability of a single dose of VIR-7832 given by intravenous (IV) infusion and determine the dose for evaluation in the Phase 2a part of the study. A total of 24 study participants will be randomized 3:1 to VIR-7832 or placebo. The Phase 2 part of the study will include three treatment arms: 50 patients randomized to VIR-7832, 50 patients to VIR-7831, and 25 patients to placebo. The co-primary endpoints are safety and virologic activity of VIR-7832 as assessed by a change in SARS-CoV-2 viral load from baseline to Day 8. The Phase 2 part of the study also will assess the T cell responses to SARS-CoV-2 of VIR-7832 and VIR-7831. The trial is being conducted at up to five sites in the UK.

About VIR-7832 / GSK4182137
VIR-7832 is a dual-action monoclonal antibody. Preclinical data suggest it has the potential to both block viral entry into healthy cells and an enhanced ability to clear infected cells. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (the virus which causes SARS), indicating that the epitope is highly conserved, which may make it more difficult for resistance to develop. VIR-7832 also has been designed to achieve high concentration in the lungs to ensure optimal penetration into airway tissues affected by SARS-CoV-2 and to have an extended half-life. Importantly, VIR-7832 has been engineered to potentially enhance virus-specific T cell function, which could help treat and/or prevent COVID-19 infection.

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About the Vir and GSK Collaboration
In April 2020, Vir and GSK entered into a collaboration to research and develop solutions for coronaviruses, including SARS-CoV-2, the virus that causes COVID-19. The collaboration uses Vir’s proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options to help address the current COVID-19 pandemic and future outbreaks. The companies will leverage GSK’s expertise in functional genomics and combine their capabilities in CRISPR screening and artificial intelligence to identify anti-coronavirus compounds that target cellular host genes. They will also apply their combined expertise to research SARS-CoV-2 and other

coronavirus vaccines.

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 SARS-CoV-2, hepatitis B virus, influenza A, human immunodeficiency virus and tuberculosis. For more information, please visit www.vir.bio.

About GSK
GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. For further information please visit www.gsk.com/about-us.

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 "may," "will," "plan," "potential," "aim," "promising" 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. Forward-looking statements contained in this press release include, but are not limited to, statements regarding the potential benefits of VIR-7832 and VIR-7831 in the treatment of COVID-19, the potential benefits of participating in the AGILE study, and statements around the expected timing of the Phase 1b/2a clinical trial. Many factors may cause differences between current expectations and actual results, including delays or failures in planned patient enrollment or retention, clinical site activation rates or clinical trial enrollment rates that are lower than expected, unexpected safety or efficacy data observed during preclinical or clinical studies, challenges in the treatment of hospitalized patients, difficulties in collaborating with other companies or government agencies, challenges in accessing manufacturing capacity, successful development and/or commercialization of alternative product candidates by our competitors, changes in expected or existing competition, delays in or disruptions to our business or clinical trials due to the COVID-19 pandemic, geopolitical changes or other external factors, and unexpected litigation or other disputes.

GSK Cautionary Statement Regarding Forward-Looking Statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk Factors" in the company's Annual Report on Form 20-F for 2019 and as set out in GSK's "Principal risks and uncertainties" section of the Q2 Results and any impacts of the COVID-19 pandemic.

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