Vir Biotechnology and GSK Start Phase 2/3 Study of COVID-19 Antibody Treatment

August 31, 2020

- *Phase 2/3 COMET-ICE study will investigate the safety and efficacy of antibody treatment in preventing hospitalization due to COVID-19*

- *Potential for initial study results to be available before the end of 2020, with early access to the antibody treatment as soon as the first half of 2021*

SAN FRANCISCO and LONDON, Aug. 31, 2020 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) and GlaxoSmithKline plc (LSE/NYSE: GSK) announced that the first patient was dosed last week in a Phase 2/3 study with VIR-7831 (also known as GSK4182136), a fully human anti-SARS-CoV-2 (Severe Acute Respiratory Syndrome coronavirus-2) monoclonal antibody, for the early treatment of COVID-19 in patients who are at high risk of hospitalization.

The aim of the COMET-ICE (COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early) study, which will enroll approximately 1,300 patients worldwide who have early symptomatic infection, is to assess whether VIR-7831, as a single-dose monoclonal antibody, can prevent hospitalization due to COVID-19. Initial results may be available before the end of this year, with complete results expected in the first quarter of 2021, and potentially early access to the antibody treatment as soon as the first half of 2021. Last week's initiation of the study follows the signing of a collaboration between the two companies in April 2020 to research and develop solutions for coronaviruses.

George Scangos, Ph.D., chief executive officer, Vir, said: "Treating those with early COVID-19 disease so that it doesn't become worse is critical both for the patients and for society. Hospital systems are overwhelmed worldwide, with new infections continuing to strain already limited resources. This study is designed to demonstrate whether VIR-7831 can significantly reduce the need for hospitalization in high-risk individuals, such as the elderly or those with pre-existing conditions such as lung or heart disease."

Dr. Hal Barron, chief scientific officer and president R&D, GSK, said: "Monoclonal antibodies directed against the SARS-CoV-2 virus could provide an effective and immediate immune response to COVID-19, bypassing the need for our body to produce its own antibodies, which is particularly important in the absence of an effective vaccine. This study will assess the ability of VIR-7831 to prevent high-risk individuals from progressing to severe disease, and in future studies we will also test the antibody's ability to prevent infection in high-risk patients and to reduce disease severity in patients who are already hospitalized."

Monoclonal antibodies that neutralize SARS-CoV-2 infection, the virus that causes COVID-19, are being investigated as a potential therapeutic and prophylactic approach against the disease. They are produced, or cloned, from immune cells in a laboratory. Vir's antibody platform has identified unique antibodies from survivors that may work by blocking the virus from infecting new cells (neutralization) and by recruiting the immune system to eliminate infected cells (effector function).

A key feature of SARS-CoV-2 is the spike protein that covers the virus' outer surface. The virus uses these spike proteins to bind to and enter human cells, leading to infection. It is hypothesized that monoclonal antibodies directed against the spike proteins could represent a therapeutic approach against COVID-19. Pre-clinical studies with VIR-7831, which was identified through Vir's antibody platform, showed affinity for the SARS-CoV-2 spike protein and high potency in neutralizing SARS-CoV-2, suggesting a high barrier to resistance and an ability to recruit immune cells to kill already infected cells. In addition, VIR-7831 has been designed to enhance lung bioavailability.

The COMET-ICE multi-center, double-blind, placebo-controlled Phase 2/3 study investigating VIR-7831 in patients with mild or moderate COVID-19 who are at high risk of progression to severe disease comprises two parts. The first part (the Lead-In phase) will serve as the first-in-human assessment. The Lead-In phase will assess the safety and tolerability of a single 500 mg intravenous (IV) infusion of VIR-7831 or placebo over a 14-day period in non-hospitalized patients. It aims to recruit 20 patients across the United States. Following this initial safety assessment, the second part (the Expansion phase) will progress with the aim of reducing the need for hospitalization. The Expansion phase will assess the safety and efficacy of a single IV infusion of VIR-7831 or placebo in approximately 1,300 non-hospitalized participants globally. The primary efficacy endpoint is the proportion of patients with mild or moderate COVID-19 who worsen, as defined by the need for hospitalization or death, within 29 days of randomization.

The COMET clinical development program for VIR-7831 also includes two additional planned trials—one for the treatment of severely ill hospitalized patients and another for the prophylaxis of symptomatic infection.

Later this year, the companies expect to start a Phase 2 trial of their other investigational SARS-CoV-2 neutralizing antibody, VIR-7832, which shares the same characteristics as VIR-7831 but may also function as a therapeutic and/or prophylactic T cell vaccine.

About VIR-7831 / GSK4182136
VIR-7831 (GSK4182136) 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-7831/GSK4182136 has been engineered to enhance lung bioavailability and have an extended half-life.

About VIR-7832
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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 hepatitis B virus, influenza A, SARS-CoV-2, 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. 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 potential benefits of Vir's collaboration with GSK, the expected timing of clinical study results for VIR-7831, Vir-7831's potential to treat COVID-19 and its expected clinical activity, clinical trials for VIR-7832, the ability of VIR-7832 to function as a therapeutic and/or prophylactic vaccine and its clinical activity, as well as Vir's ability to identify new anti-viral antibodies and its technologies, as well as Vir's ability to address the current COVID-19 pandemic and future outbreaks of the disease. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data or results observed during clinical trials, challenges in identifying new anti-viral antibodies, challenges in neutralizing SARS-CoV-2 or in identifying and inhibiting cellular targets, difficulties in obtaining regulatory approval, challenges in accessing manufacturing capacity, clinical site activation rates or clinical trial enrollment rates that are lower than expected, changes in expected or existing competition, delays in or disruptions to Vir's business or clinical trials due to the COVID-19 pandemic, geopolitical changes or other external factors, and unexpected litigation or other disputes. 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.

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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