Vir Biotechnology and GSK Announce Start of NIH-Sponsored ACTIV-3 Trial Evaluating VIR-7831 in Hospitalized Adults with COVID-19

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– Randomized, placebo-controlled, multicenter, global Phase 3 trial will investigate the safety and efficacy of VIR-7831 in hospitalized adults with COVID-19 –

SAN FRANCISCO and LONDON, Dec. 17, 2020 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) and GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the first patient has been dosed in a new sub-trial of the National Institutes of Health's (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Program Phase 3 clinical trial. This trial is designed to evaluate the safety and efficacy of VIR-7831 for the treatment of hospitalized adults with COVID-19. VIR-7831 (also known as GSK4182136) is a fully human anti-SARS-CoV-2 (Severe Acute Respiratory Syndrome coronavirus-2) investigational monoclonal antibody that was selected based on its potential to neutralize the virus, kill infected cells, provide a high barrier to resistance and achieve high concentrations in the lungs (one of the major sites of infection).

ACTIV-3 is one of several ongoing trials in the NIH's ACTIV program, an NIH led public-private partnership designed to accelerate development of the most promising treatments and vaccine candidates for COVID-19. ACTIV-3 has been designed as a "master protocol" that allows for the simultaneous evaluation of multiple investigational therapeutics as they become available, but within the same clinical trial structure, across multiple trial sites.

George Scangos, Ph.D., chief executive officer of Vir, said: "Recent data suggest that the neutralizing activity of antibodies may be insufficient to protect hospitalized adults from the most severe consequences of COVID-19. We are hopeful that the differentiating factors and broad anti-coronavirus activity of VIR-7831 may allow it to help those patients and add to our preparedness for related coronaviruses that could emerge in the future."

Dr. Hal Barron, chief scientific officer and president R&D, GSK, said: "With new infection and hospitalization rates reaching record highs, the world needs multiple options to help combat this pandemic. We are developing solutions to fight this virus, from prevention through treatment, to provide relief from COVID-related illness. Our treatment option, VIR-7831, which has a high barrier to resistance and has the potential to neutralize the virus and kill infected cells, could allow this treatment to be effective for patients in hospital settings, where other antibodies have so far not shown an impact."

In addition to the Phase 3 ACTIV-3 trial, VIR-7831 is also being evaluated in the global Phase 2/3 COMET-ICE (COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early) trial for the early treatment of COVID-19 in adults at high risk of hospitalization. The Phase 3 part of the COMET-ICE trial is assessing the safety and efficacy of a single intravenous (IV) infusion of VIR-7831 or placebo in approximately 1,300 non-hospitalized participants globally. The primary efficacy endpoint is the proportion of adults who have progression of COVID-19 as defined by the need for hospitalization or death within 29 days of randomization. The COMET clinical development program for VIR-7831 also includes a planned Phase 3 trial for the prevention of symptomatic infection.

ACTIV-3 Clinical Trial Design
The ACTIV-3 trial arm evaluating VIR-7831 will initially compare 300 participants who have been hospitalized with mild to moderate COVID-19 with fewer than 13 days of symptoms, who will receive either VIR-7831 or placebo. Participants also will receive standard care for COVID-19, including the FDA-approved antiviral remdesivir. Five days after dosing, participants' clinical status will be assessed, based on need for supplemental oxygen, mechanical ventilation, or other supportive care. If the VIR-7831 treatment arm appears to have a positive benefit:risk profile, the trial will enroll an additional 700 participants, including those who are more severely ill (i.e., adults with organ failure requiring mechanical support, or COVID-19-associated dysfunction of organs other than the lungs). Trial participants will be followed for 90 days following enrollment to analyze their response to treatment. The primary efficacy endpoint is the participants' sustained recovery for 14 days after release from the hospital.

About VIR-7831 / GSK4182136
VIR-7831 (GSK4182136) is a monoclonal antibody for which preclinical data suggest its ability to neutralize SARS-CoV-2 live virus in vitro and in vivo. 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 resistance to develop. VIR-7831/GSK4182136 has been engineered with the potential to enhance lung bioavailability and have an extended half-life.

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. 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-7831 in treating hospitalized patients with COVID-19, the potential benefits of participating in the ACTIV-3 trial, the ability of using a combination of a potent effector function and neutralization capabilities in enhancing the efficacy of monoclonal antibodies to treat hospitalized patients, the efficacy and safety of a single intravenous (IV) infusion of VIR-7831, Vir's plans around the evaluation of interim analyses and the expected timing of clinical study results for VIR-7831, the ability of VIR-7831 to prevent symptomatic infection, the clinical trial design around ACTIV-3 as well as statements around the potential benefits of Vir and GSK's collaboration in addressing the current COVID-19 pandemic and future outbreaks of the disease. 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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