Vir Biotechnology and GSK Provide Update on NIH-Sponsored ACTIV-3 Trial Evaluating VIR-7831 in Hospitalized Adults with COVID-19

March 3, 2021

SAN FRANCISCO and LONDON, March 03, 2021 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) and GlaxoSmithKline plc (LSE/NYSE: GSK) today provided an update on the VIR-7831 (GSK4182136) arm of the National Institutes of Health's (NIH) Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Program Phase 3 clinical trial. The companies were informed that while VIR-7831 met initial pre-specified criteria to continue to the next phase of the ACTIV-3 trial and there were no reported safety signals, sensitivity analyses of the available data raised concerns about the magnitude of potential benefit. The independent Data and Safety Monitoring Board (DSMB) has recommended that the VIR-7831 arm of the trial be closed to enrollment while the data mature. The companies will continue discussions with the NIH about appropriate ways to further assess the potential of VIR-7831 in the hospitalized population as all parties gain a fuller understanding of the still-emerging data.

The DSMB recommendation was based on a routine, pre-planned safety and efficacy data review of the first 300 patients hospitalized with COVID-19 enrolled in ACTIV-3.

George Scangos, Ph.D., chief executive officer of Vir, **said:** "While we are disappointed with the recommendation of the DSMB, we are encouraged by the safety profile of VIR-7831 and by the possibility of a benefit on top of remdesivir and corticosteroids in this advanced cohort of patients. We want to thank NIH for their work to assess the benefits of VIR-7831 and other agents, and look forward to working with them to further understand the potential of VIR-7831 to provide a benefit in this population. In addition, we are eagerly anticipating the upcoming data from the Phase 3 COMET-ICE trial in newly-diagnosed COVID-19 patients at high risk of hospitalization."

Christopher Corsico, Senior Vice President Development, GSK, said: "We want to thank the patients who participated in this study and the NIH for investing in the ACTIV trial to evaluate the four monoclonal antibodies, as it recognizes the need for differentiated treatments, especially as new variants emerge globally. These and other anticipated data will provide valuable insights about how VIR-7831 can contribute to the fight against this pandemic."

VIR-7831 is an investigational, dual-action monoclonal antibody that has been shown in preclinical trials to both block viral entry into healthy cells and clear infected cells, which may protect patients from disease progression.

The antibody has also shown the ability to neutralize the SARS-CoV-2 live virus by binding to a highly conserved epitope of the spike protein, which may make it more difficult for resistance to develop. So far, the variants of concern, including the UK, South African and Brazilian variants, do not overlap with the VIR-7831 targeted epitope of the virus, and, therefore, VIR and GSK believe that it should maintain full activity against these strains.

In addition to the ACTIV-3 trial, VIR-7831 is also being evaluated in the outpatient setting in the following clinical trials:

- **COMET-ICE** (COVID-19 Monoclonal antibody Efficacy Trial – Intent to Care Early): A Phase 3 trial to evaluate VIR-7831 for the early treatment of COVID-19 in adults at high risk of hospitalization or death.
- **BLAZE-4** (sponsored by Eli Lilly and Company): A Phase 2 trial designed to assess the safety and efficacy of Eli Lilly's bamlanivimab (LY-CoV555) alone and bamlanivimab with other neutralizing antibodies, including VIR-7831, versus placebo in low-risk adults with mild to moderate COVID-19.

Additionally, VIR-7831, along with VIR-7832, will be evaluated in the Phase 1b/2a National Health Service-supported AGILE trial in adults with mild to moderate COVID-19. VIR-7832 is the second monoclonal antibody from the Vir-GSK collaboration to be investigated as a potential COVID-19 treatment.

VIR-7831 and VIR-7832 are investigational compounds, not approved by the U.S. Food and Drug Administration or any other regulatory authority.

About VIR-7831 / GSK4182136
VIR-7831 is an investigational dual-action SARS-CoV-2 monoclonal antibody. Preclinical data suggest it has the potential to both block viral entry into healthy cells and clear infected cells. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (the virus that causes SARS), indicating that the epitope is highly conserved, which may make it more difficult for resistance to develop. VIR-7831, which incorporates Xencor's Xtend™ technology, 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.

About VIR-7832 / GSK4182137
VIR-7832 is an investigational dual-action SARS-CoV-2 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 that causes SARS), indicating that the epitope is highly conserved, which may make it more difficult for resistance to develop. VIR-7832, which incorporates Xencor's Xtend and other Fc technologies, 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 also has been engineered to potentially enhance virus-specific T cell function, which could help treat and/or prevent COVID-19 infection.

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.

GSK commitment to tackling COVID-19
GSK's response to COVID-19 has been one of the broadest in the industry, with two potential treatments in addition to our vaccine candidates in development.

GSK is collaborating with several organizations on COVID-19 vaccines by providing access to our adjuvant technology. In addition to work with Sanofi, our collaboration with Medicago on an adjuvanted, protein-based vaccine candidate is now in late-stage clinical trials. An earlier stage collaboration with SK Bioscience is also ongoing, with funding from CEPI and Bill and Melinda Gates Foundation, to develop differentiated, affordable COVID-19 vaccines for supply globally through the COVAX facility. The use of an adjuvant can be of particular importance in a pandemic since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced, contributing to protecting more people.

GSK is also working with mRNA specialist, CureVac, to jointly develop next generation, multi-valent mRNA vaccines for COVID-19 with the potential to address multiple emerging variants in one vaccine. GSK will also support manufacturing of up to 100m doses of CureVac's first generation COVID-19 vaccine, if approved.

GSK is also exploring potential therapeutic or treatment options for COVID-19 patients. We are collaborating with Vir Biotechnology to develop existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options for COVID-19.

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 COVID-19, hepatitis B virus, influenza A and human immunodeficiency virus. 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 timing of availability of clinical data, program updates and data disclosures related to VIR-7831, the ability of VIR-7831 and VIR-7832 to treat and/or prevent COVID-19, the potential of VIR-7831 in the hospitalized population, the ability of VIR-7831 to neutralize the SARS-CoV-2 live virus and the ability of VIR-7831 to maintain full activity against variant strains of the virus. 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 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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Source: Vir Biotechnology, Inc.