GSK and Vir Biotechnology announce submission of Emergency Use Authorization request to FDA for VIR-7831 for the early treatment of COVID-19

PUBLISHED MAR 26, 2021
BY GSK

For media and investors only

Issued: London, UK and San Francisco, US

GlaxoSmithKline plc and Vir Biotechnology, Inc. today announced the submission of an application to the U.S. Food and Drug Administration (FDA) requesting Emergency Use Authorization (EUA) for VIR-7831 (GSK4182136) an investigational dual-action SARS-CoV-2 monoclonal antibody, for the treatment of adults and adolescents (aged 12 years and older weighing at least 40 kg) with mild-to-moderate COVID-19 who are at risk for progression to hospitalisation or death.

The FDA EUA submission is based on an interim analysis of efficacy and safety data from the Phase 3 COMET-ICE (COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early) trial, which evaluated VIR-7831 as monotherapy for the early treatment of COVID-19 in adults at high risk of hospitalisation. Results of the interim analysis, based on data from 583 patients enrolled in the trial, demonstrated an 85% ($p=0.002$) reduction in hospitalisation or death in those receiving VIR-7831 compared to placebo, the primary endpoint of the trial. As a result, the Independent Data Monitoring Committee recommended that the trial be stopped for enrolment due to evidence of profound efficacy. Data from the registrational COMET-ICE trial also will form the basis for a Biologics License Application (BLA) submission to the FDA.

Preclinical data suggest VIR-7831 targets a highly conserved epitope of the spike protein, which may make it more difficult for resistance to

develop. New in vitro data from pseudotyped virus assays published online in bioRxiv in March 2021 support this hypothesis as they demonstrate that VIR-7831 maintains activity against current circulating variants of concern including the UK, South African and Brazilian variants. Based on additional soon to be published preclinical data, VIR-7831 also appears to maintain activity against the California variant.

GSK and Vir will continue discussions with the European Medicines Agency (EMA) and other global regulators to make VIR-7831 available to patients with COVID-19 as soon as possible.

The multi-centre, double-blind, placebo-controlled COMET-ICE trial investigated VIR-7831 in adults with mild or moderate COVID-19 who are at high risk of progression to severe disease. The Phase 2 lead-in portion of the trial, which served as the first-in-human assessment, evaluated the safety and tolerability of a single 500 mg intravenous (IV) infusion of VIR-7831 or placebo over a 14-day period in 21 non-hospitalised adults enrolled across the United States. In October 2020, based on a positive evaluation of safety and tolerability data of VIR-7831 from the lead-in part of the trial by an Independent Data Monitoring Committee, the trial began enrolling patients in North America and additional sites in South America and Europe in the global Phase 3 portion of the trial.

In March 2021, an Independent Data Monitoring Committee recommended that the COMET-ICE trial be stopped for enrolment due to evidence of profound efficacy but is continuing to follow study participants for 24 weeks. Additional results, including epidemiology and virology data, will be forthcoming once the trial is completed.

The Phase 3 portion of the trial assessed the safety and efficacy of a single IV infusion of VIR-7831 (500 mg) or placebo in non-hospitalised participants globally. The interim analysis included 291 patients in the treatment arm and 292 patients in the placebo arm. Among those studied, 63% were Hispanic or Latinx and 7% were Black or African American. The primary efficacy endpoint is the proportion of patients who have progression of COVID-19 as defined by the need for hospitalisation for at least 24 hours or death within 29 days of randomisation.

About the VIR-7831 Clinical Development Programme

In addition to the COMET-ICE trial, the full COMET clinical development programme for VIR-7831 includes:

- COMET-PEAK: An ongoing Phase 2 trial with two parts: to compare the safety and viral kinetics of 500 mg intramuscularly (IM) administered VIR-7831 to 500 mg intravenously administered VIR-7831 among low-risk adults with mild to moderate COVID-19 and to evaluate the similarity in pharmacokinetics between VIR-7831 manufactured by different processes.

- COMET-TAIL: A Phase 3 trial expected to begin in the second quarter of 2021 in high-risk adults to assess whether IM-administered VIR-7831 can reduce hospitalisation or death due to COVID-19.

- COMET-STAR: A Phase 3 trial expected to begin in the second quarter of 2021 in uninfected adults at high risk to determine whether IM-administered VIR-7831 can prevent symptomatic infection.

VIR-7831 is also being evaluated in the outpatient setting in BLAZE-4, a Phase 2 trial sponsored by Eli Lilly and Company, designed to assess the safety and efficacy of Eli Lilly's bamlanivimab (LY-CoV555) alone and bamlanivimab with other neutralising 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 three potential treatments in addition to our vaccine candidates in development.

GSK is collaborating with several organisations on COVID-19 vaccines by providing access to our adjuvant technology. In addition to our work with Medicago, a collaboration with Sanofi on an

adjuvanted, protein-based vaccine candidate is now in Phase 2. An earlier stage collaboration with SK Bioscience is also ongoing. SK Bioscience receives funding from CEPI and the 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 and 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.

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. We recently reported that an Independent Data Monitoring Committee recommended that the Phase 3 COMET-ICE trial evaluating VIR-7831 as monotherapy for the early treatment of COVID-19 in adults at high risk of hospitalisation be stopped for enrolment due to evidence of profound efficacy, based on an interim analysis of data from the trial. We are seeking Emergency Use Authorization in the US and authorisations in other countries. We are also assessing whether an investigational monoclonal antibody, otilimab, can help severely ill COVID-19 patients aged over 70 who experience an overreaction of their immune system.

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 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.

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 preclinical and clinical data, clinical development 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, the ability of VIR-7831 to maintain full activity against variant strains of the virus, Vir’s collaboration with GSK, and statements related to regulatory authorizations and approvals, including Vir’s plans to submit a BLA to the FDA and continue discussions with the EMA and other global regulators. Many factors may cause differences between current expectations and actual results, including challenges in obtaining regulatory approval, 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 in the Company's

Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

Press release distributed by Wire Association on behalf of GSK, on Mar 26, 2021. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/gsk-and-vir-biotechnology-announce-submission-of-emergency-use-authorization-request-to-fda-for-vir-7831-for-the-early-treatment-of-covid-19-1957

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk
Website: https://www.gsk.com/
Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK
Twitter - http://twitter.com/GSK
Youtube - http://www.youtube.com/GSK
Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/
