GSK and Vir Biotechnology announce EMA review of dual-action monoclonal antibody VIR-7831 for the early treatment of COVID-19

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GSK and Vir continue discussions with global regulators to make VIR-7831 available to patients with COVID-19.

GlaxoSmithKline plc and Vir Biotechnology, Inc. today announced that the European Medicines Agency (EMA) has started a review of VIR-7831 (GSK4182136), an investigational dual-action SARS-CoV-2 monoclonal antibody, for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with COVID-19 who do not require oxygen supplementation and who are at high risk of progressing to severe COVID-19.

The review is being carried out by the EMA's Committee for Human Medicinal Products (CHMP) under Article 5(3) of Regulation 726/2004 and will provide EU-wide recommendations for national authorities who may take evidence-based decisions on the early use of the medicine, ahead of any formal Marketing Authorisation Application.

The review will include data from 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 randomised patients, 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. The CHMP review will also consider data on the medicine's quality and safety.

This week, the Australian Therapeutic Goods Administration (TGA), part of the Department of Health, granted VIR-7831 a provisional determination. VIR-7831 is the first anti-SARS-CoV-2 monoclonal antibody to have been granted this designation which provides a formal and transparent mechanism for accelerating the registration of promising new medicines with preliminary clinical data.

VIR-7831 is an investigational compound and has not been granted a marketing authorisation anywhere in the world. An Emergency Use Authorization (EUA) application for VIR-7831 has been submitted to the US Food and Drug Administration (FDA).

Preclinical data suggest VIR-7831 targets a highly conserved epitope of the SARS-CoV-2 spike protein, which may make it more difficult for resistance to develop. New in vitro data from pseudotyped virus assays published online in bioRxiv 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 preclinical data published in

GSK is planning to submit a full Marketing Authorisation Application (MAA) to the EMA which will include the data from the COMET-ICE trial.

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. Topline data announced in March 2021 showed that in combination, the two monoclonal antibodies demonstrated a 70% relative reduction of patients with persistently high viral load at day 7

compared to placebo.

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 and have not been granted marketing authorisations anywhere in the world.

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.

VVir 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.

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.

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 EMA’s

review of VIR-7831, 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 to treat and/or prevent COVID-19 (as monotherapy and in combination with bamlanivimab), 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 plans to continue discussions with the FDA 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. 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.

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