GSK and Vir Biotechnology announce the start of the EMA rolling review of VIR-7831 (sotrovimab) for the early treatment of COVID-19

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- Rolling review will evaluate sotrovimab in adults and adolescents with COVID-19 who do not require oxygen supplementation and who are at risk of progressing to severe COVID-19

- Review will support a formal Marketing Authorisation Application

- GSK and Vir continue discussions with global regulators to make sotrovimab available to patients with COVID-19

GlaxoSmithKline plc and Vir Biotechnology, Inc. today announced that the European Medicines Agency (EMA) has started a rolling review of data on sotrovimab (previously VIR-7831), 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 coronavirus disease 2019 (COVID-19) who do not require oxygen supplementation and who are at risk of progressing to severe COVID-19.

The EMA will evaluate all data on sotrovimab, including evidence from clinical trials, as they become available. The rolling review will continue until enough evidence is available to support a formal marketing authorisation application. The EMA will assess the medicine’s compliance with the usual standards for efficacy, safety and quality. While the overall review timeline cannot be forecast yet, the process should be quicker than a regular evaluation due to the

time gained during the rolling review.

The review of the data is being carried out by the EMA's Committee for Medicinal Products for Human Use (CHMP). The decision to start the rolling review is based on the 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 sotrovimab 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 hospitalisations over 24 hours or deaths in those receiving sotrovimab compared to placebo, the primary endpoint of the trial.

Separately, the CHMP is also reviewing sotrovimab under Article 5(3) of Regulation 726/2004 and is expected to 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.

Sotrovimab is an investigational compound and has not been granted a marketing authorisation anywhere in the world.

An Emergency Use Authorization (EUA) application for sotrovimab has been submitted to the US Food and Drug Administration (FDA). Sotrovimab is also under review by other global regulators including Health Canada under the expedited Interim Order application pathway for COVID-19 drugs.

About the COMET-ICE Study Design

The multi-center, double-blind, placebo-controlled, Phase 3 COMET-ICE trial investigated sotrovimab in adults with mild or moderate COVID-19 at high risk of progression to severe disease.

This Phase 3 trial evaluated the safety and efficacy of a single IV infusion of sotrovimab (500 mg) or placebo in non-hospitalised participants globally. The efficacy 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 was 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 randomization.

In March 2021, an Independent Data Monitoring Committee recommended that the COMET-ICE trial be stopped for enrolment due to evidence of efficacy and is continuing to follow study participants for 24 weeks. Additional results, including epidemiology and virology data, will be forthcoming once the trial is completed and will be published in a peer reviewed medical journal. In COMET-ICE, infusion- related reactions were reported at a low frequency (1%) in sotrovimab-treated patients and was comparable to the incidence in the placebo arm (1%). These infusion-related reactions occurring within 24 hours of study treatment included pyrexia, chills, dizziness, dyspnea, pruritus and rash, which were Grade 1 (mild) or Grade 2 (moderate) and no events consistent with antibody dependent enhancement (ADE) were observed.

About the Sotrovimab Clinical Development Program

In addition to the COMET-ICE trial, the full COMET clinical development program for sotrovimab includes:

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

- COMET-TAIL: A Phase 3 trial expected to begin in the second quarter of 2021 as an early treatment in high-risk adults to assess whether IM-administered sotrovimab 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 sotrovimab can prevent symptomatic infection.

Sotrovimab was also 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 bamlanivimab (LY-CoV555) alone and bamlanivimab with other neutralizing antibodies, including sotrovimab, versus placebo in low-risk adults with mild to moderate COVID-19. An interim analysis found that bamlanivimab (700 mg) co-administered

with sotrovimab (500 mg) demonstrated a 70% relative reduction of patients with persistently high viral load at day 7 compared to placebo, meeting the primary endpoint. The three companies are engaging with the FDA regarding the possible co-administration of bamlanivimab and sotrovimab for the treatment of COVID-19.

Additionally, sotrovimab, along with VIR-7832, is being 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.

Sotrovimab 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, and less likely to mutate over time. Sotrovimab, 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 sotrovimab as monotherapy for the early treatment of COVID-19 in adults at high risk of hospitalisation be stopped for enrolment due to

evidence of efficacy, based on an interim analysis of data from the trial. An Emergency Use Authorization (EUA) application for sotrovimab has been submitted to the US Food and Drug Administration (FDA). 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.

Vir's Commitment to COVID-19

Vir was founded with the mission of addressing the world's most serious infectious diseases. In 2020, Vir responded rapidly to the COVID-19 pandemic by leveraging our unique scientific insights and industry-leading antibody platform to explore multiple monoclonal antibodies as potential therapeutic or preventive options for COVID-19. Sotrovimab is the first SARS-CoV-2-targeting antibody we advanced into the clinic. It was carefully selected for its unique characteristics demonstrated during preclinical research, including a high barrier to resistance and dual-action ability to both block the virus from entering healthy cells and clear infected cells. Sotrovimab has since demonstrated positive monotherapy results in a Phase 3 clinical trial for the early treatment of COVID-19 in high-risk adult patients, and proven in preclinical studies to retain activity against all known circulating COVID-19 variants of concern. Vir is continuing to pursue novel therapeutic and prophylactic solutions to combat SARS-CoV-2 and future coronavirus pandemics, both independently and in collaboration with our partners.

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.

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 timing and availability of sotrovimab to providers and patients, including arrangements with commercial payers, the timing of availability of clinical data, program updates and data disclosures related to sotrovimab, the ability of sotrovimab and VIR-7832 to treat and/or prevent COVID-19, the potential of sotrovimab in the hospitalised population, the ability of sotrovimab to neutralise the SARS-CoV-2 live virus, statements related to the planned full analysis of the COMET-ICE trial, and statements related to marketing authorisations and regulatory authorisations and approvals, including plans and discussions with the EMA, FDA, Health Canada and other global regulators. 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 hospitalised patients, difficulties in collaborating with other companies or government agencies, challenges in accessing manufacturing capacity, successful development and/or commercialisation of alternative product candidates by Vir’s competitors, 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 US 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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