MHRA grants conditional marketing authorisation1 for COVID-19 treatment Xevudy (sotrovimab)

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- Conditional marketing authorisation has been granted for Great Britain and is based on Phase III data showing sotrovimab reduced the risk of hospitalisation or death by 79% in adult patients with an increased risk of progressing to severe COVID-19

- A supply agreement reached with UK government will enable access to sotrovimab for UK patients

GlaxoSmithKline plc (LSE/NYSE: GSK) and Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted a conditional marketing authorisation for Xevudy (sotrovimab) for the treatment of symptomatic adults and adolescents (aged 12 years and over and weighing at least 40 kg) with acute COVID-19 infection who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID infection. It is recommended that Xevudy is administered within 5 days of onset of symptoms of COVID-19. In the coming weeks, UK patients at increased risk of severe complications of COVID-19 will be able to access sotrovimab following a supply agreement reached earlier with the UK government. The Conditional Marketing Authorisation covers England, Scotland, and Wales. Supply of sotrovimab in Northern Ireland is enabled under the regulation 174 of the Human Medicines Regulations 2012,

George Katzourakis, Senior Vice President, Europe, GSK said:

> The conditional marketing authorisation in Great Britain, coupled with the supply agreement, is a testament to the critical need to make sotrovimab available in the UK as the pandemic continues to progress. We believe it is important to ensure that we have treatments ready and available, especially early treatment options, for a broad group of patients at increased risk of progressing to severe COVID-19.

George Scangos, PhD, Chief Executive Officer of Vir, said:

> We are pleased with the UK Government's recognition of the role that monoclonal antibodies, like sotrovimab, have to play in addressing this pandemic. With clinical data demonstrating a 79% reduction in hospitalisations for more than 24 hours or death in non-hospitalised patients, we are confident sotrovimab will continue to be a critical tool in the fight against COVID-19. We look forward to making sotrovimab available to the NHS and patients in the UK and to continuing our efforts to increase access worldwide.

The design of sotrovimab, a monoclonal antibody, is based on the natural antibodies humans already make. In clinical trials sotrovimab was shown to significantly reduce the risk of hospitalisation or death among high-risk adult outpatients with mild to moderate COVID-19. The final analysis from the COMET-ICE trial demonstrated a 79% reduction (adjusted relative risk reduction 95% CI, p

GSK and Vir are committed to ongoing evaluation of sotrovimab as the COVID-19 landscape continues to evolve at different rates across the globe and new variants of concern and interest emerge. Sotrovimab 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 conserved, which may make it more difficult for resistance to develop. This indicates potential for sotrovimab to be effective across multiple variants of concern. Updated in vitro data, published in bioRxiv(the pre-print server for biology) demonstrate that sotrovimab retains activity against all current tested variants of concern and interest of the SARS-CoV-2 virus as defined by the World Health Organisation (WHO), plus others, including, but not limited to, Delta (B.1.617.2), Delta Plus (AY.1 or AY.2) and Mu (B.1.621). Based on the sequence of the Omicron variant, we believe sotrovimab is likely to maintain activity and potency against this variant

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at Yellow Card Scheme - MHRA. Adverse events should also be reported to GSK at uksafety@gsk.com.

Sotrovimab is an investigational SARS-CoV-2 neutralising monoclonal antibody. 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 conserved, which may make it more difficult for resistance to develop. Sotrovimab, which incorporates Xencor's Xtend™ technology, has also been designed to achieve high concentration in the lungs to optimise penetration into airway tissues affected by SARS-CoV-2 and to extend antibody elimination half-life.

About the sotrovimab clinical development programme

- COMET-ICE: a Phase III, multi-centre, double-blind, placebo-controlled trial investigated intravenous (IV) infusion of sotrovimab in adults with mild-to-moderate COVID-19 at increased risk of progression to severe disease, who are not hospitalised and not requiring oxygen. The final COMET-ICE trial results in the full trial population of 1,057 participants demonstrated a 79% reduction (adjusted relative risk reduction) (p

COMET-TAIL: a Phase III randomised, multi-centre, open label, non-inferiority trial of intramuscular (IM) versus intravenous (IV) administration of sotrovimab for the early treatment of mild-to-moderate COVID-19 in high-risk non-hospitalised adult and paediatric patients (12 years of age and older). The primary endpoint of the study was met and a Press Release with further details has been issued previously.

- COMET-PEAK: A Phase II randomised, multi-centre, parallel group trial evaluating IV and IM administration of sotrovimab in outpatients with mild-to-moderate COVID-19.

- GSK and Vir are also partnering to investigate the use of sotrovimab in uninfected immunocompromised adults to determine whether sotrovimab can prevent symptomatic COVID-19 infection. GSK and Vir are supporting investigator sponsored studies and fostering scientific collaborations with experienced investigators and networks,

Limitations of Authorized Use

Sotrovimab is not authorized for use in patients:

- who are hospitalized due to COVID-19, OR

- who require oxygen therapy due to COVID-19, OR

- who require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity).

Benefit of treatment with sotrovimab has not been observed in patients hospitalized due to COVID-19. SARS-CoV-2 monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

About the GSK and Vir 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 potential treatments in addition to our vaccine candidates in development with partner organisations.

GSK is collaborating with several organisations on COVID-19 vaccines by providing access to our adjuvant technology. We are working with Sanofi S.A., Medicago Inc. and SK bioscience Co., Ltd. to develop adjuvanted, protein-based vaccine candidates, and all are

now in Phase III clinical trials. 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 protect more people in need.

GSK is also working with mRNA specialist, CureVac N.V., to jointly develop next generation, optimised mRNA vaccines for COVID-19 with the potential to address multiple emerging variants in one vaccine.

GSK is also exploring treatments for COVID-19 patients, collaborating with Vir Biotechnology to investigate monoclonal antibodies that could be used as therapeutic or preventive options for COVID-19.

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 Vir advanced into the clinic. It was carefully selected for its demonstrated promise in preclinical research, including an anticipated high barrier to resistance and potential ability to both block the virus from entering healthy cells and clear infected cells. 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 its partners.

GSK is a science-led global healthcare company. For further information please visit www.gsk.com/about-us.

Vir Biotechnology is a commercial-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, GSK's Q3 Results 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 ability of sotrovimab to treat and/or prevent COVID-19 either through IV or IM administration, Vir's collaboration with GSK, an agreement with the UK Government to supply sotrovimab, binding agreements to supply sotrovimab worldwide, the timing and expected number of therapeutic doses that Vir and GSK will be able to supply to governments and patients, planned discussions with regulatory authorities, the timing of availability of clinical data, program updates and data disclosures, the clinical development program for sotrovimab, and the ability of sotrovimab to maintain activity against circulating variants of concern and interest. 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 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 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.

[1] CMAs are valid for one year and will be renewable annually and may be granted in specific circumstances for medicinal products that fulfil an unmet medical need, where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon.

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