Primary endpoint met in COMET-TAIL Phase III trial evaluating intramuscular administration of sotrovimab for early treatment of COVID-19

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- COMET-TAIL Phase III data demonstrated that intramuscular administration of sotrovimab was non-inferior and offered similar efficacy to intravenous administration for high-risk populations

- The trial enrolled participants during the Delta variant wave of the pandemic in the US

GlaxoSmithKline plc (LSE/NYSE: GSK) and Vir Biotechnology, Inc. (Vir) (Nasdaq: VIR) today announced headline data from the randomised, multi-centre, open-label COMET-TAIL Phase III trial, which achieved its primary endpoint, demonstrating intramuscular (IM) administration of sotrovimab was non-inferior to intravenous (IV) administration for the early treatment of mild-to-moderate COVID-19 in high-risk, non-hospitalised adults and adolescents (12 years of age and older).

The COMET-TAIL Phase III trial was designed to evaluate the efficacy, safety, and tolerability of sotrovimab delivered via IM administration compared to IV administration in high-risk patients up to seven days after symptom onset. In the IM administration (500mg) arm of the trial, there was a 2.7% rate of progression to hospitalisation for more than 24 hours or death through Day 29 of the trial, compared to 1.3% in the IV administration arm (also 500mg). The adjusted difference between the IM and IV arms of the trial was 1.07% with a 95% confidence interval (CI) of -1.25% to 3.39%. The upper bound of the 95% CI is

within the predetermined 3.5% non-inferiority margin set for the trial's primary endpoint in consultation with the US Food and Drug Administration (FDA).

In addition, there were low rates of serious adverse events and Grade 3-4 adverse events (≤1% in both arms, for both measures) observed in the headline data.

The companies plan to progress regulatory submissions globally, including ongoing discussions with the FDA regarding the existing Emergency Use Authorization for sotrovimab.

Dr Hal Barron, Chief Scientific Officer and President, said:

> I am pleased that today's results demonstrated similar efficacy for sotrovimab when injected directly into the muscle compared to administered intravenously, potentially offering a more convenient option for patients. We look forward to working with regulatory authorities to help make this new option available to appropriate patients with COVID-19.

George Scangos, Ph.D., chief executive officer of Vir, said:

> This trial was conducted during the height of circulation of the Delta variant, with significant enrollment in Florida – a hot spot for this particular variant and where hospitalisation rates averaged more than 10 percent of confirmed cases. We designed sotrovimab to stand up to the variants that we anticipated would occur, and these data demonstrate that sotrovimab administered via IV or IM could prove important in the fight against COVID-19 following authorisation. As we approach the third year of the pandemic, we can expect that multiple treatment options will continue to be needed, particularly for high-risk patients with complex health needs.

Today's update follows announcements in the first half of 2021 regarding the COMET-ICE Phase III trial, which investigated IV infusion of sotrovimab in adults with mild or moderate COVID-19 at high-risk of progression to severe disease. The final COMET-ICE trial results in the full study population of 1057 participants, demonstrated a 79% reduction in hospitalisation and death at Day 29 vs placebo.

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 highly 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 ensure optimal penetration into airway tissues affected by SARS-CoV-2 and to have an extended half-life.

Updated in vitro data, published in bioRxiv, demonstrate that sotrovimab retains activity against all current variants of concern and interest of the SARS-CoV-2 virus as defined by the World Health Organisation, plus others, including, but not limited to, Delta (B.1.617.2), Delta Plus (AY.1 or AY.2) and Mu (B.1.621).

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 high-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 trial's primary endpoint was met, and headline data demonstrated that intramuscularly administered sotrovimab was non-inferior and offered similar efficacy to intravenous administration for high-risk populations. The COMET-TAIL trial enrolled a total of 983 patients up to seven days after onset of symptoms. The trial originally included three arms: 500mg of sotrovimab given intravenously, and two intramuscular arms, consisting of 500mg and a low dose of 250mg. An independent safety monitoring committee recommended enrolment in the 250mg arm be discontinued after a greater number of hospitalisations in that arm was noted. The 500mg dose arms were recommended to continue with enrolment as planned. The companies plan to submit the full COMET-TAIL data set to a peer-reviewed journal for publication in the first quarter of 2022.

- 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. Data available to date from open label Part B of the trial (500mg IV vs. 500mg IM) demonstrated equivalence on the virological response between the IM and IV arms, while also showing an acceptable tolerability profile for IM with only 10/82 participants (12%) reporting any injection site reaction, all of which were low grade (Grade 1). The companies plan to submit the full COMET-PEAK data set to a peer-reviewed journal for publication.

- 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 both experienced investigators and networks, who are involved in the continuum of care of immunocompromised patients, to understand the role sotrovimab for prophylaxis could play in this population. Discussions with regulatory authorities regarding the prophylaxis program will take place in due course.

About global access to sotrovimab

- Sotrovimab is authorised for emergency use in the United States and received a positive scientific opinion under Article 5(3) of Regulation 726/2004 from the Committee for Human Medicinal Products (CHMP) in the EU. Sotrovimab has been granted a provisional marketing authorisation in Australia and a conditional marketing authorisation in Saudi Arabia. In Japan it has been approved via the Special Approval for Emergency Pathway. Temporary authorisations have been granted in Bahrain, Brazil, Canada, Egypt, Italy, Kuwait, Oman, Qatar, Singapore, Switzerland, Thailand and the United Arab Emirates.

- Sotrovimab is supplied in several countries around the world, including through national agreements in the United States, Japan, Australia, Canada, Singapore and UAE. We have also signed a Joint Procurement Agreement with the European Commission to supply doses of sotrovimab. Additional agreements are yet to be announced due to confidentiality or regulatory requirements.

Sotrovimab in the United States

The following is a summary of information for sotrovimab. Healthcare providers in the U.S. should review the Fact Sheets for information

about the authorised use of sotrovimab and mandatory requirements of the EUA. Please see the FDA Letter of Authorisation, full Fact Sheet for Healthcare Providers, and full Fact Sheet for Patients, Parents, and Caregivers.

Sotrovimab has been authorized by the U.S. FDA for the emergency use described below. Sotrovimab is not FDA-approved for this use.

Sotrovimab is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of sotrovimab under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product sotrovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

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.

Important Safety Information

Sotrovimab is contraindicated in patients who have a history of anaphylaxis to sotrovimab or to any of the excipients in the

formulation.

There are limited clinical data available for sotrovimab. Serious and unexpected adverse events may occur that have not been previously reported with sotrovimab use.

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of sotrovimab. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive care.

Infusion-related reactions, occurring during the infusion and up to 24 hours after the infusion, have been observed with administration of sotrovimab. These reactions may be severe or life threatening.

Signs and symptoms of infusion-related reactions may include: fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (eg, atrial fibrillation, sinus tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vaso-vagal reactions (eg, pre-syncope, syncope), dizziness and diaphoresis.

Consider slowing or stopping the infusion and administer appropriate medications and/or supportive care if an infusion-related reaction occurs.

Hypersensitivity reactions occurring more than 24 hours after the infusion have also been reported with the use of SARS-CoV-2 monoclonal antibodies under Emergency Use Authorization.

Clinical Worsening After SARS-CoV-2 Monoclonal Antibody Administration

Clinical worsening of COVID-19 after administration of SARS-CoV-2 monoclonal antibody treatment has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia (eg, atrial fibrillation, tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to SARS-

CoV-2 monoclonal antibody use or were due to progression of COVID-19.

Limitations of Benefit and Potential for Risk in Patients with Severe COVID-19

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. Therefore, 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.

Hypersensitivity adverse reactions have been observed in 2% of patients treated with sotrovimab and 1% with placebo in COMET-ICE.

The most common treatment-emergent adverse events observed in the sotrovimab treatment group in COMET-ICE were rash (1%) and diarrhea (2%), all of which were Grade 1 (mild) or Grade 2 (moderate). No other treatment-emergent adverse events were reported at a higher rate with sotrovimab compared to placebo.

USE IN SPECIFIC POPULATIONS

There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcome. Sotrovimab should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.

There are no available data on the presence of sotrovimab in human milk, the effects on the breastfed infant, or the effects on milk production. Individuals with COVID-19 who are breastfeeding should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

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 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, Medicago and SK bioscience 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, 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 SARSCoV-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, 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, plans to progress regulatory submissions globally, including with the FDA regarding the existing EUA for sotrovimab, planned discussions with other global

regulatory agencies, 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.

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