GSK and Vir Biotechnology announce United States government agreements to purchase sotrovimab, a COVID-19 treatment

PUBLISHED NOV 17, 2021
BY GSK

For media and investors only

Issued: London UK and San Francisco US

- US government contracts for approximately $1 billion(USD) now in place to purchase sotrovimab, further expanding access nationwide

- This brings the total number of doses secured through binding agreements to more than 750,000 globally

- Final data from the COMET-ICE Phase III trial showed sotrovimab reduces hospitalisation and risk of death by 79% in adults with mild-to-moderate COVID-19 who are at high risk of progression to severe disease

- In vitro data indicate sotrovimab maintains activity against the Delta variant of concern and other variants being monitored

GlaxoSmithKline plc (LSE/NYSE: GSK) and Vir Biotechnology, Inc. (Nasdaq: VIR) today announced US government contracts totalling approximately $1 billion(USD) to purchase sotrovimab, an investigational monoclonal antibody for the early treatment of COVID-19, which the US Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) in May 2021. GSK will supply these doses to the US government by December 17, 2021, enabling further expanded nationwide access to sotrovimab for patients.

In addition to the doses that will be supplied this year, the US government will have the option to purchase additional doses through

March 2022.

Including the contracts announced today, GSK and Vir have received binding agreements for the sale of more than 750,000 doses of sotrovimab worldwide, with additional doses reserved through other agreements including the previously announced Joint Procurement Agreement with the European Commission.

Sotrovimab is an FDA EUA authorised investigational single-dose intravenous (IV) infusion SARS-CoV-2 monoclonal antibody. Under the EUA, sotrovimab can be used for the treatment of mild-to-moderate COVID-19 in adults and paediatric patients (12 years of age and older weighing at least 40 kg) with positive test results for COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalisation or death.

Dr Hal Barron, Chief Scientific Officer and President R&D, GSK, said:

> Given the large number of patients who continue to become ill with COVID-19 across many regions in the US, there is an ongoing need for access to effective treatments. We are proud to work with the US government to help make sotrovimab available for these patients.

George Scangos, Ph.D., Chief Executive Officer of Vir, said:

> Monoclonal antibodies play an essential role in the treatment of certain patients with COVID-19, and we're grateful that this agreement will allow more healthcare providers and patients who are at high risk for progression to severe COVID-19 to access sotrovimab. Given ongoing evidence, which demonstrates its ability to maintain activity against the tested circulating variants of concern, including Delta, we are confident sotrovimab will continue to be important in the fight against COVID-19.

The US government purchase was funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response through Department of Defense – contract numbers W58P0521C0008 and W58P0522C0002.

In June 2021, GSK and Vir announced confirmatory full results for the COMET-ICE Phase III trial, which resulted in a 79% reduction (adjusted relative risk reduction) (p

The companies also recently 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 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 companies plan to progress regulatory submissions globally.

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. 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 Organization, plus others, including, but not limited to, Delta (B.1.617.2), Delta Plus (AY.1 or AY.2) and Mu (B.1.621).

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.

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 European Union (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 (UAE).

- Sotrovimab is supplied in several countries around the world, including through national agreements in the United States, Japan, Australia, Canada, Singapore and the 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.

About the sotrovimab clinical development programme

- COMET-ICE: a Phase III, multi-centre, double-blind, placebo-controlled trial investigated 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 IM versus 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 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. 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.

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 Authorization, 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 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.

Editor's Note: Financial considerations

The total value of the two current agreements with the US government for supply of sotrovimab in 2021 is about $1 billion, with GSK supplying the agreed number of doses to the US government by December 17, 2021. This new agreement is included within GSK's financial guidance of an expected contribution to 2021 Adjusted EPS from COVID-19 solutions of 7% to 9% at CER.

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, whether or not the US government will exercise their option, 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.

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Press release distributed by Wire Association on behalf of GSK, on Nov 17, 2021. For more information subscribe and follow us.

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