Preclinical studies demonstrate sotrovimab retains activity against the full combination of mutations in the spike protein of the Omicron SARS-CoV-2 variant

PUBLISHED DEC 7, 2021
BY GSK

For media and investors only

Issued: London UK and San Francisco US

- New preclinical findings generated through in vitro testing of sotrovimab against the complete pseudo-virus, updated to bioRxiv

- Data build on promising signal published last week, underscoring the importance of sotrovimab for early treatment of COVID-19

- Sotrovimab is authorised and available for the treatment of early COVID-19 in the US and multiple countries around the world

GlaxoSmithKline plc (LSE/NYSE: GSK) and Vir Biotechnology, Inc. (Nasdaq: VIR) today announced an update to preclinical data on bioRxiv, a preprint server, demonstrating that sotrovimab, an investigational monoclonal antibody, retains in vitro activity against the full known Omicron spike protein, the new SARS-CoV-2 variant (B.1.1.529). The preclinical data was generated through pseudo-virus testing of the combined known mutations of the Omicron variant, which included the maximum number of changes (37 mutations) identified to date in the spike protein. These findings build on the initial preclinical data generated through pseudo-virus testing, provided last week, showing sotrovimab retained in vitro activity against key individual mutations of the Omicron variant, including those found in the binding site of sotrovimab. These data add to the growing body of preclinical evidence demonstrating that sotrovimab retains activity against all tested variants of concern.

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

> Sotrovimab is the first monoclonal antibody to report preclinical data demonstrating activity against all tested SARS-CoV-2 variants of concern and interest to date, including Omicron, as well as the still prevalent and highly contagious Delta variant. Given the less than three-fold neutralization shift demonstrated in the pre-clinical pseudo-virus assay, which falls below the FDA authorized fact sheet guidance of less than a 5-fold change, we are confident that sotrovimab will continue to provide significant benefit for the early treatment of patients hoping to avoid the most severe consequences of COVID-19.

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

> From the outset of our collaboration with Vir we hypothesized that sotrovimab would have a high barrier to resistance and thus could deliver best-in-class potential for the early treatment of patients with COVID-19. These pre-clinical data demonstrate the potential for our monoclonal antibody to be effective against the latest variant, Omicron, plus all other variants of concern defined to date by the WHO, and we look forward to discussing these results with regulatory authorities around the world.

Sotrovimab is an investigational SARS-CoV-2 neutralising monoclonal antibody. The antibody binds to an epitope on SARS-CoV-2 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, Inc.'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.

Pre-clinical data, published in bioRxiv, demonstrate that sotrovimab retains activity against all currently tested variants of concern and interest of the SARS-CoV-2 virus as defined by WHO, plus others, including but not limited to Delta (B.1.617.2), Delta Plus (AY.1 or AY.2), Mu (B.1.621) and Omicron (B.1.1.529).

About the sotrovimab clinical development program

- COMET-ICE: a phase III, multi-centre, double-blind, placebo-controlled trial investigated an 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 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 IM administered sotrovimab was non-inferior and offered similar efficacy to IV administration for high-risk populations. The companies plan to submit the complete 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 complete COMET-PEAK data set to a peer-reviewed journal for publication in due course.

- GSK and Vir are also partnering to assess the use of sotrovimab in uninfected immunocompromised adults to determine whether sotrovimab can prevent symptomatic COVID-19 infection. GSK and Vir support investigator-sponsored studies and foster scientific collaborations with experienced investigators and networks 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 occur in due course.

About global access to sotrovimab

Sotrovimab is authorised for emergency use in the United States. Xevudy (sotrovimab) received a positive scientific opinion under Article 5(3) of Regulation 726/2004 from the Committee for Human Medicinal Products in the EU, conditional marketing authorisation by the UK Medicines and Healthcare Products Regulatory Agency, provisional marketing authorisation in Australia, and conditional

marketing authorisation in Saudi Arabia. It has been approved via the Special Approval for Emergency Pathway in Japan. Temporary authorisations for sotrovimab have been granted in a dozen countries.

GSK and Vir also recently submitted the Marketing Authorisation Application to the European Medicines Agency for Xevudy for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40kg) with coronavirus disease 2019 (COVID-19) who do not require oxygen supplementation and who are at risk of progressing to severe COVID-19.

Sotrovimab is supplied in several countries worldwide, including through national agreements in the United States, United Kingdom, Japan, Australia, Canada, Singapore, Switzerland, and the United Arab Emirates. The companies 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 US should review the Fact Sheets for information about the authorized use of sotrovimab and mandatory requirements of the EUA. Please see the Food and Drug Administration (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 US 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. 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 (e.g., 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 (e.g., 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 (e.g., 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 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 SA, 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 protecting more people in need.

GSK is also working with mRNA specialist, CureVac NV, 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/aboutus.

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.

Reference Cathcart AL, Havenar-Daughton C, Lempp FA, et al. The

dual function monoclonal antibodies VIR-7831 and VIR-7832 demonstrate potent in vitro and in vivo activity against SARS-CoV-2. bioRxiv. 2021. Updated manuscript submitted and online pre-print publication pending.

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, including Omicron. 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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