GSK and Vir Biotechnology Announce United States Government Agreement to Purchase Additional Supply of Sotrovimab, Authorized for the Early Treatment of COVID-19

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– 600,000 additional doses to be supplied to the US government for distribution in Q1 2022, enabling further access to sotrovimab nationwide –

– Brings total number of doses secured to date through binding agreements to approximately 1.7 million globally –

– Preclinical data generated through both pseudo-virus and live virus testing demonstrate sotrovimab retains activity against all tested SARS-CoV-2 variants of concern including Delta and Omicron –

LONDON and SAN FRANCISCO, Jan. 11, 2022 (GLOBE NEWSWIRE) -- GlaxoSmithKline plc (LSE/NYSE: GSK) and Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the US government will purchase an additional 600,000 doses of sotrovimab, an investigational monoclonal antibody for the early treatment of COVID-19, enabling further nationwide access to sotrovimab for patients. The additional 600,000 doses will be delivered throughout the first quarter of 2022. This agreement is an amendment to earlier commitments announced with the US government in November 2021.

Including the commitments announced today, GSK and Vir have received binding agreements for the sale of approximately 1.7 million doses of sotrovimab worldwide. In addition, today's agreement also includes the option for the US government to purchase further additional doses in the second quarter of 2022.

Sotrovimab, which was granted Emergency Use Authorization (EUA) by the US Food and Drug Administration (FDA) in May 2021, is an 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 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.

GSK and Vir expect to manufacture approximately 2 million doses globally in the first half of 2022 and additional doses in the second half of the year.

Maya Martinez-Davis, President, US Pharmaceuticals, GSK, said: "We are proud to continue to work with the US government to bring sotrovimab to patients who need it, especially as the Omicron variant continues to grow in prevalence across the country. We understand the role we can play in supporting the ongoing pandemic response, and our teams are working with urgency to explore options to expand our supply capacity so we can support more patients in 2022."

George Scangos, Ph.D., Chief Executive Officer of Vir, said: "As the Omicron variant continues its rapid spread alongside the still prevalent Delta variant, we are pleased to once again work with the US government to provide more access to sotrovimab for people in the US at high risk of progression to severe COVID-19. Data from multiple pseudo-virus and live virus preclinical studies, generated by industry and academia, continue to demonstrate that sotrovimab retains activity against all tested variants of concern and interest. We are proud of our ongoing contributions to the fight against the COVID-19 pandemic here in the US and around the world."

The Biomedical Advanced Research and Development Authority (BARDA), part of the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), collaborated with the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) and Army Contracting Command to purchase contract numbers W58P0521C0008 and W58P0522C0002.

In June 2021, GSK and Vir announced confirmatory full results for the COMET-ICE Phase 3 trial examining use of sotrovimab for early treatment of mild-to-moderate COVID-19 in high-risk, non-hospitalized adults. The trial met the primary endpoint with a 79% reduction (adjusted relative risk reduction) ($p<0.001$) in all-cause hospitalizations for more than 24 hours or death due to any cause by Day 29 compared to placebo. In absolute numbers, 30 (6%) of the 529 patients in the placebo arm progressed, compared to six (1%) of the 528 patients receiving sotrovimab. In clinical trials conducted to date, sotrovimab has been well-tolerated. The most common adverse reactions are hypersensitivity and infusion-related reactions, seen in approximately 2% and 1% of cases, respectively.

GSK and Vir are committed to the 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. Preclinical pseudovirus data, published in *bioRxiv*, demonstrate that sotrovimab retains activity against all tested variants of concern and interest of the SARS-CoV-2 virus as defined by the World Health Organization, including, but not limited to, Omicron (B.1.1.529), Delta (B.1.617.2), Delta Plus (AY.1 or AY.2) and Mu (B.1.621). Preclinical live virus testing has also been completed with data, recently published in *bioRxiv*, further demonstrating that sotrovimab retains activity against the Omicron variant.

About Sotrovimab
Sotrovimab is an investigational SARS-CoV-2 neutralizing 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.

About Global Access to Sotrovimab
Sotrovimab is authorized for emergency use in the US and has been granted a marketing authorization in the EU, conditional marketing authorization in Great Britain, provisional marketing authorization in Australia, and conditional marketing authorization in Saudi Arabia. It has also been approved via

Japan's Special Approval for Emergency Pathway. Temporary authorizations for sotrovimab have also been granted in 12 other countries.

Sotrovimab is supplied in several countries worldwide, including through national agreements in the US, UK, Japan, Australia, Canada, Singapore, Switzerland, and the United Arab Emirates. The companies are also supplying sotrovimab to participating Member States of the EU through a Joint Procurement Agreement with the European Commission. Additional agreements are yet to be disclosed 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.

Authorized Use
The US FDA has issued an 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 40kg) 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

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

WARNINGS AND PRECAUTIONS
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.

ADVERSE EVENTS
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
Pregnancy
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.

Lactation
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, GSK and Vir 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 the Company's vaccine candidates in development with partner organisations.

GSK is collaborating with several organisations on COVID-19 vaccines by providing access to its adjuvant technology. The Company is 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.

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

About Vir Biotechnology
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 2021 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, the timing and expected number of therapeutic doses that Vir will be able to supply to patients, whether or not the US government will exercise their option, and the ability of sotrovimab to maintain activity against circulating variants of concern and interest, including Delta and 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 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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