Xevudy (Sotrovimab) Granted Marketing Authorization by the European Commission for the Early Treatment of COVID-19

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LONDON and SAN FRANCISCO, Dec. 17, 2021 (GLOBE NEWSWIRE) -- GlaxoSmithKline plc (LSE/NYSE: GSK) and Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the European Commission (EC) has granted marketing authorization to *Xevudy* (sotrovimab) for the early treatment of COVID-19. Sotrovimab is now approved in the European Union (EU) for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40kg) with COVID-19 who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19.

The grant of the marketing authorization in the EU is a result of the positive opinion issued on December 16 by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP).

In July 2021, GSK and Vir announced a Joint Procurement Agreement (JPA) with the EC to supply up to 220,000 doses of sotrovimab. Following the grant of the marketing authorization in the EU, Member States participating in the JPA can now order sotrovimab to support their pandemic responses.

Dr Hal Barron, Chief Scientific Officer and President R&D, GSK, said: "Since the start of the pandemic we have seen an unprecedented effort by governments, academia and industry to find solutions to help as many people as quickly as possible. COVID-19 therapeutics are an important part of the solution. We have already been working to lay the foundation for more patients across Europe to access sotrovimab through the Joint Procurement Agreement with the European Commission. With today's marketing authorization we are now able to expand access, and we are discussing with governments how we can bring sotrovimab to more patients."

George Scangos, Ph.D., Chief Executive Officer of Vir, said: "The grant of the marketing authorization in the European Union for sotrovimab marks yet another important milestone in our efforts to combat COVID-19, as it allows us to expand access across multiple countries working to address this challenge. Given recent preclinical data from our own labs, as well as that of other independent labs, demonstrating that sotrovimab retains activity against the rapidly spreading Omicron variant and all other currently tested variants of concern and interest, we remain confident in the critical role of sotrovimab and look forward to further contributing to the fight against this pandemic."

The grant of the marketing authorization in the EU is based on data from the COMET-ICE Phase 3 trial, demonstrating that intravenous treatment with sotrovimab resulted in 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, meeting the primary endpoint of the trial. 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. Updated in vitro 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).

About *Xevudy* (Sotrovimab)
Xevudy (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. *Xevudy* (sotrovimab) 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 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 have also announced a JPA with the EC to supply doses of sotrovimab to participating Member States of the EU. Additional agreements are yet to be disclosed due to confidentiality or regulatory requirements.

Important Information About Sotrovimab in the European Union

For more information on the marketing authorization in the European Union, please review the Summary of Product Characteristics (SmPC). Healthcare professionals should look out for side effects and take appropriate action.

Reporting of Suspected Adverse Reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system

listed in Appendix V.

Warnings and Precautions

Hypersensitivity Reactions including Anaphylaxis

Hypersensitivity reactions, including anaphylaxis, have been reported with administration of sotrovimab (see section 4.8 of the SmPC). If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, administration should be discontinued immediately and appropriate medications and/or supportive care should be given.

Infusion-Related Reactions

Infusion-related reactions (IRRs) have been observed with intravenous administration of monoclonal antibodies (see section 4.8 of the SmPC). These reactions may be severe or life-threatening. If an IRR occurs, the infusion may be interrupted, slowed or stopped.

Adverse Reactions

The most common adverse reactions were hypersensitivity reactions (2%) and infusion-related reactions (1%). The most serious adverse reaction was anaphylaxis (0.05%).

Pregnancy

There are no data from the use of sotrovimab in pregnant women. Animal studies have not been evaluated with respect to reproductive toxicity. In a cross-reactive binding assay using a protein array enriched for human embryofetal proteins, no off-target binding was detected. Since sotrovimab is a human immunoglobulin G (IgG), it has the potential for placental transfer from the mother to the developing fetus. The potential treatment benefit or risk of placental transfer of sotrovimab to the developing fetus is not known. Sotrovimab should be used during pregnancy only if the expected benefit to the mother justifies the potential risk to the fetus.

Lactation

It is not known whether sotrovimab is excreted in human milk or absorbed systemically after ingestion. Administration of sotrovimab while breast-feeding can be considered when clinically indicated.

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 Emergency Use Authorization (EUA). 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 USC § 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 COVID19. SARS-CoV-2 monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID19 requiring high flow oxygen or mechanical ventilation.

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.

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 organizations.

GSK is collaborating with several organizations 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 3 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, optimized 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, 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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