Vir Biotechnology Announces First Marketing Authorization for its First Commercial Product, Sotrovimab, Granted in Australia

August 23, 2021

– First monoclonal antibody authorized in Australia –

SAN FRANCISCO, Aug. 23, 2021 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced the first marketing authorization, granted in Australia, for its first commercial product, sotrovimab, developed in partnership with GlaxoSmithKline (GSK). This announcement follows news shared by GSK Australia that the Australian Therapeutic Goods Administration (TGA) has granted provisional marketing authorization for sotrovimab (under the brand name, Xevudy®), a monoclonal antibody for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with COVID-19 who do not require initiation of oxygen due to COVID-19 and who are at increased risk of progression to hospitalization or death. Sotrovimab is the first monoclonal antibody approved in Australia. As part of its overarching effort to address COVID-19, the Australian Government also recently announced an agreement to purchase sotrovimab, the first supply of which arrived in the country last week.

The TGA had previously granted sotrovimab a provisional determination in April, which provides a mechanism for accelerating the provisional marketing authorization of promising new medicines. This approval pathway allows companies to apply for registration of medicines for conditions with high unmet clinical need based on promising early clinical data.

Globally, sotrovimab is authorized for emergency use in the U.S., received a positive scientific opinion from the Committee for Human Medicinal Products (CHMP) in the European Union (EU), and has been granted temporary authorization in Bahrain, Canada, Egypt, Italy, Kuwait, Qatar, Singapore and the United Arab Emirates.

George Scangos, Ph.D., chief executive officer of Vir, said: “The provisional approval of sotrovimab in Australia marks an important milestone for Vir, as it is the first marketing authorization of our first commercial product. It also represents an important step forward in the Australian Government’s efforts to combat the pandemic and prevent the most severe effects of COVID-19, particularly in the face of new and emerging variants. We eagerly anticipate additional regulatory decisions around the world in the coming months and look forward to working with our partner, GSK, to expand patient access to a much-needed treatment option that continues to demonstrate, in vitro, its ability to retain activity against the tested, currently circulating variants of concern and interest, including Delta and Delta Plus.”

The regulatory applications currently under assessment around the world, include results of the Phase 3 COMET-ICE (COVID-19 Monoclonal antibody Efficacy Trial - Intent to Care Early) trial, which resulted in a 79% reduction (adjusted relative risk reduction) ($p<0.001$) in all-cause hospitalization 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 vitro data, published in bioRxiv also demonstrate that sotrovimab retains activity against currently circulating variants of concern and interest of the SARS-CoV-2 virus including Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2), Delta Plus (AY.1 or AY.2), Epsilon (B.1.427/B.1.429), Eta (B.1.525), Gamma (P.1), Iota (B.1.526), Kappa (B.1.617.1) and Lambda (C.37), as well as new variants from Bristol (B.1.1.7+E484K) and Cameroon (B.1.619), which predominantly includes both N440K and E484K mutations that may lead to reduced activity for other neutralizing monoclonal antibodies against the SARS-CoV-2 virus.

This announcement is part of a collaboration between Vir and GSK, signed in April 2020, to research and develop solutions for coronaviruses, including SARS-CoV-2, the virus that causes COVID-19. GSK is responsible for the commercial marketing of sotrovimab around the world.

About Sotrovimab (Outside of Australia)
Sotrovimab is an investigational SARS-CoV-2 monoclonal antibody. Preclinical data suggest it has the potential to both block viral entry into healthy cells and clear infected cells. 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, also has 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.

Important Information about Sotrovimab in Australia

Minimum Product Information
XEVUDY ▼ (sotrovimab) Concentrated injection solution for infusion

Indications: XEVUDY has provisional approval for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with coronavirus disease 2019 (COVID-19) who do not require initiation of oxygen due to COVID-19 and who are at increased risk of progression to hospitalization or death. The decision has been made on the basis of short term efficacy and safety data. Continued approval of this indication depends on the evidence of longer term efficacy and safety from ongoing clinical trials and post-market assessment.

Contraindications: Hypersensitivity to the active substance or any of the excipients

Precautions: Hypersensitivity reactions. In a study in patients hospitalized with COVID-19, hypersensitivity reactions, including serious reactions such as anaphylaxis, have been reported following infusion of sotrovimab. If signs and symptoms of a clinically significant hypersensitivity reaction occur, immediately discontinue administration and initiate appropriate supportive care.

In COMET-ICE, mild to moderate hypersensitivity reactions have been observed. If mild to moderate hypersensitivity reactions occur, consider slowing or stopping the infusion along with appropriate supportive care. Pregnancy: Category B2. Lactation: No data in human milk. Fertility: No data in

humans. Pediatric use: Safety and efficacy in children under 12 years of age or weighing less than 40kg has not yet been established. For further details, please refer to the full Product Information (PI).

Interactions: No formal interaction studies have been performed. The efficacy and safety of sotrovimab in subjects who have received a COVID-19 vaccine at any time prior to its administration has not been established. The receipt of a COVID-19 vaccine within 48 hours prior to, or 4 weeks following treatment with XEVUDY has not been studied.

Adverse reactions: Diarrhea, hypersensitivity reactions (includes rash, dermatitis contact, skin reaction, hypersensitivity, multiple allergies, infusion-related reaction and bronchospasm). One case of anaphylaxis was reported following infusion of sotrovimab in a study in hospitalized patients; the patient received epinephrine and the event resolved. This is not a complete list, see full PI.

Dosage and Administration: Adults and adolescents (12 years or older and weighing at least 40 kg): recommended dose is a single 500 mg dose administered as an intravenous infusion over 30 minutes. It is recommended that XEVUDY is administered within 5 days of onset of symptoms of COVID-19. XEVUDY must be diluted prior to administration and must not be administered as an intravenous push or bolus injection. XEVUDY should be administered in healthcare facilities in which patients can be monitored during and for one hour after administration of XEVUDY. As part of risk stratification of patients, the pivotal consideration is the comorbidities, alongside age, particularly multiple comorbidities. XEVUDY should not be used in patients hospitalized due to COVID-19. For further details, please refer to the full PI.

XEVUDY Min PI v1. For further details, please refer to the full PI.
▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

Full Product Information is available by contacting GSK Australian Medical Information at +61 1800 033 109; or, if dialing from the US, contact the GSK US Response Center (Rx) at +1 888 825 5249.

PBS INFORMATION: This product is not listed on the PBS. For information on GSK products or to report an adverse event involving a GSK product, please contact GSK Australian Medical Information at +61 1800 033 109; or, if dialing from the US, contact the GSK US Response Center (Rx) at +1 888 825 5249. GlaxoSmithKline Australia Pty Ltd. ABN 47 100 162 481. Melbourne, VIC. XEVUDY is a registered trademark of the GSK group of companies. PI-8601 Date of approval: August 2021

Sotrovimab in the United States
Healthcare providers in the U.S. should review the Fact Sheets for information on the authorized use of sotrovimab and mandatory requirements of the 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 of the emergency use of sotrovimab under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the is terminated or revoked sooner.

Authorized Use in the United States
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.

Please see the FDA Letter of Authorization, full Fact Sheet for Healthcare Providers, and full Fact Sheet for Patients, Parents, and Caregivers.

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 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.

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 provisional approval of sotrovimab in Australia, the ability of sotrovimab to treat and/or prevent COVID-19, the supply of sotrovimab to the Australian government and the timing of that delivery, statements related to additional regulatory authorizations and approvals around the world and their anticipated timing 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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