



Data Suggest Sotrovimab Retains Neutralizing Activity Against Omicron Subvariant BA.2

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*– Pseudovirus results being shared with government and regulatory authorities;
publication in bioRxiv anticipated in the coming week; additional live virus testing underway –*

SAN FRANCISCO, Feb. 09, 2022 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that preclinical data suggest that sotrovimab, an investigational monoclonal antibody authorized for emergency use in the United States and developed in conjunction with GlaxoSmithKline, retains neutralizing activity against the BA.2 subvariant of Omicron. These pseudovirus results are being shared with government and regulatory authorities around the world and the Company expects to publish data on *bioRxiv* in the coming week, with live virus data to follow.

"Our view of the data is that they support the ongoing role of sotrovimab as a critical treatment in the fight against the continuously evolving SARS-CoV-2 virus," said George Scangos, Vir's chief executive officer. "We note recent conclusions from another lab, which state that no approved or authorized monoclonal antibodies for treatment retain activity against all subvariants of Omicron. We are therefore pleased to share that, based on our pseudovirus and extensive pharmacokinetic data, we believe that the 500 mg dose of sotrovimab is sufficient to retain activity against the BA.2 variant, just as it has against all other variants of concern and interest."

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 European Union (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. Vir and GlaxoSmithKline 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 Emergency Use Authorization (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 Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Authorized use

The 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 COVID19 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.

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. We routinely post information that may be important to investors on our website at 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 the ability of sotrovimab to treat and/or prevent COVID-19, Vir's collaboration with GlaxoSmithKline, 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 preclinical data, program updates and data disclosures and publications related to sotrovimab, the clinical development program for sotrovimab, and the ability of sotrovimab to maintain activity against circulating variants of concern and interest, including the BA.2 sublineage of 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, 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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