



Vir Biotechnology Announces Positive Final Draft Guidance on Sotrovimab from the UK's National Institute for Health and Care Excellence (NICE)

February 22, 2023

Final draft guidance based on cost effectiveness evaluation of sotrovimab

SAN FRANCISCO, Feb. 22, 2023 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the UK's National Institute for Health and Care Excellence (NICE) provided positive final draft guidance recommending the use of sotrovimab, an investigational SARS-CoV-2 neutralizing monoclonal antibody, in adults who do not need supplemental oxygen for COVID-19 and who have an [increased risk for progression to severe COVID-19](#) where nirmatrelvir/ritonavir (Paxlovid) is contraindicated or unsuitable. Due to existing inventory, no meaningful additional sales of sotrovimab in the UK are anticipated in 2023.

"We welcome the final draft guidance from NICE which we believe is particularly meaningful as the organization's recommendations are informed by independent committees that aim to provide guidance to healthcare professionals on the best care options available to benefit their patients," said George Scangos, Ph.D., Chief Executive Officer of Vir. "With this recommendation, sotrovimab continues to be an important option for appropriate patients around the world and we remain committed to working with our partner GSK to ensure patients in need have access to it."

This final draft guidance provides recommendations to the UK's National Health Service on the future routine commissioning of therapeutics for people with COVID-19 while COVID-19 is an endemic disease. NICE expects to publish its final recommendations on medicines to treat COVID-19 in March 2023.

Sotrovimab has obtained emergency authorization, temporary authorization or marketing approval (under the brand name Xevudy®) for early treatment of COVID-19, supplying more than 40 countries. Sotrovimab is not authorized in the US.

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 conserved. 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.

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 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 and hepatitis D viruses, influenza A and human immunodeficiency virus. Vir routinely posts information that may be important to investors on its website.

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 GSK, the ability of sotrovimab to maintain activity against currently circulating variants, and Vir's plans and expectations for sotrovimab, and its COVID-19 portfolio. 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. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Early-stage clinical trial results may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented. 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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