Vir Biotechnology Announces First Patient Dosed in Groundbreaking Phase 2 Trial of VIR-2482 for Antibody Prophylaxis of Influenza A

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– First clinical trial evaluating the role of a monoclonal antibody in preventing seasonal flu –

– Announcement follows recent U.S. government award from the Biomedical Advanced Research and Development Authority supporting development of VIR-2482 –

SAN FRANCISCO, Oct. 18, 2022 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the first participant has been dosed in the Phase 2 PENINSULA (Prevention of Illness Due to Influenza A) trial evaluating VIR-2482 for the prevention of illness due to influenza A. This trial is the first to evaluate the role of a monoclonal antibody in the prevention of influenza A illness.

VIR-2482 is an intramuscularly administered investigational monoclonal antibody that has demonstrated *in vitro* the ability to neutralize all major strains of influenza A that have arisen since the 1918 Spanish flu pandemic. It is designed to be a universal prophylactic against both seasonal and pandemic influenza A, and has been engineered to have an extended half-life, providing the potential for protection throughout an entire flu season.

"Each year, seasonal flu is responsible for hospitalizing millions of people around the world and causing hundreds of thousands of deaths," said Phil Pang, M.D., Ph.D., executive vice president, chief medical officer and interim head of research at Vir Biotechnology. "With current flu vaccine effectiveness rates averaging 40%, additional prevention approaches are urgently needed, especially for those at highest risk. VIR-2482 has been designed as a single, easy-to-administer intramuscular dose to provide immediate protection against influenza A for the duration of the flu season, and we believe that its broad strain coverage could provide consistent, year-over-year protection against both seasonal influenza A strains and future flu pandemics. VIR-2482 has the potential to fill a critical gap in the prevention of illness, and we look forward to learning more from this new Phase 2 trial."

Design of the Phase 2 PENINSULA Trial
The multi-center, double-blind, randomized, placebo-controlled Phase 2 PENINSULA trial (ClinicalTrials.gov Identifier: NCT05567783) will evaluate the efficacy, safety and tolerability of two different doses of VIR-2482 in preventing influenza A illness in healthy adults. The dose-ranging, proof-of-concept trial will enroll approximately 3,000 men and women ages 18 to 64 without risk factors for serious complications from an influenza infection who have not received an influenza vaccination for the upcoming season.

The primary efficacy endpoint is the proportion of trial participants with protocol-defined influenza-like illness with confirmed influenza A infection compared to placebo. Other endpoints will evaluate the effect of VIR-2482 on the severity and duration of illness in trial participants with confirmed influenza A compared to placebo. Initial data are expected in mid-2023.

The Company also recently initiated a Phase 1b prophylaxis trial evaluating the safety of VIR-2482 in elderly participants (age 65 and older) receiving a flu vaccine. This population is representative of the Company's anticipated Phase 3 trial population. Initial data from that trial is expected in mid-2023.

About Seasonal and Pandemic Influenza A
Seasonal influenza is a highly contagious respiratory disease that can cause severe illness and life-threatening complications. It varies from season to season, but in past years, seasonal influenza has led to approximately 4 million hospitalizations and about 500,000 deaths a year worldwide. There remains a significant unmet need to address the shortcomings of current preventative and therapeutic options, which provide efficacy ranging from 10%-60%.

Pandemic influenza is a contagious airborne respiratory disease, which is unpredictable in timing and severity and for which humans have little or no immunity. Four influenza pandemics have occurred over the past century, with the most severe being the 1918 Spanish flu, which is estimated to have caused at least 50 million deaths worldwide.

About VIR-2482
VIR-2482 is an investigational intramuscularly administered influenza A-neutralizing monoclonal antibody. In vitro, it has been shown to cover all major strains of influenza A that have arisen since the 1918 Spanish flu pandemic. VIR-2482 is designed as a universal prophylactic for influenza A. It has the potential to overcome the limitations of current flu vaccines and lead to meaningfully higher levels of protection due to its broad strain coverage and because it does not rely on an individual to create their own protective antibody response. VIR-2482, which incorporates Xencor's Xtend™ Technology, also has been half-life engineered so a single dose has the potential to last the entire flu season. Under the collaboration agreement signed with GlaxoSmithKline (GSK) in 2021, GSK has an exclusive option to lead post-Phase 2 development and commercialization of VIR-2482.

As Vir reported in early October, the development of VIR-2482 is funded in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Number: 75A50122C00081. BARDA's initial investment of approximately $55 million will support the Phase 2 PENINSULA trial. The multi-year contract also allows for a potential total investment of up to $1 billion for the clinical development of additional future pandemic influenza monoclonal antibodies, as well as the potential development of up to 10 emerging infectious disease or Chemical, Biological, Radiological, and Nuclear medical countermeasure candidates.

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.

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," "expect," "anticipate," "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 Vir's strategy and plans, the potential benefits of VIR-2482 to protect against seasonal and pandemic influenza, the timing and design for VIR-2482's Phase 2 PENINSULA trial and Phase 1b prophylaxis trial, including anticipated timing of data readouts, statements regarding Vir's scientific and executional expertise, Vir's expectations related to the potential success of its current and future clinical development programs for influenza as well as other infectious diseases with future pandemic potential, Vir's collaboration with BARDA and risks and uncertainties associated with drug development and commercialization. Many factors may cause differences between current expectations and actual results, including risks that Vir may not fully enroll the Phase 2 PENINSULA trial or it will take longer than expected; unexpected safety or efficacy data or results observed during the Phase 2 PENINSULA trial or Phase 1b prophylaxis trial or in data readouts; the occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; uncertainty as to whether the anticipated benefits of the BARDA collaboration can be achieved; difficulties in collaborating with other companies; 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. Results in early-stage clinical trials 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 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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