Vir Biotechnology Announces Topline Data from Phase 2 PENINSULA Trial Evaluating VIR-2482 for the Prevention of Seasonal Influenza A Illness

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SAN FRANCISCO, July 20, 2023 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that the Phase 2 PENINSULA (**P**rev**E**ntio**N** of **I**ll**N**es**S** D**U**e to Inf**L**uenza **A**) trial evaluating VIR-2482 for the prevention of symptomatic influenza A illness did not meet primary or secondary efficacy endpoints. In participants who received the highest dose of VIR-2482 (1,200 mg), a non-statistically significant reduction of approximately 16% in influenza A protocol-defined illness was observed. Participants who received the highest dose showed an approximately 57% reduction in symptomatic influenza A illness, when defined according to CDC influenza-like-illness criteria, which was one of two secondary endpoints. VIR-2482 was generally well tolerated and no safety signals were identified.

PENINSULA (NCT05567783) is the first Phase 2 outpatient trial to evaluate the role of a monoclonal antibody in the prevention of influenza A illness. The dose-ranging, proof-of-concept trial enrolled approximately 3,000 men and women ages 18 to 64 without risk factors for serious complications from an influenza infection who did not receive an influenza vaccination for the flu season. The primary efficacy endpoint was the proportion of trial participants with protocol-defined influenza-like-illness[1] with PCR-confirmed influenza A infection compared to placebo. Secondary endpoints included the proportion of participants with CDC-defined influenza-like-illness[2] with PCR-confirmed influenza A infection and the proportion of participants with WHO-defined influenza-like-illness[3] with PCR-confirmed influenza A infection.

“Although, these topline data are disappointing, further analysis is necessary to better understand these outcomes, which we plan to present at a major medical congress,” said Phil Pang, M.D., Ph.D., Vir’s Executive Vice President, Chief Medical Officer and Interim Head of Research. “In the meantime, we are continuing to advance next generation solutions for serious respiratory infections, including VIR-2981, an investigational neuraminidase-targeting monoclonal antibody against both influenza A and B viruses.”

“We are grateful to all who participated in this trial, and we remain committed to the pursuit of novel therapies that have the potential to address some of the world’s most serious infectious diseases,” said Marianne De Backer, M.Sc., Ph.D., MBA, Vir’s Chief Executive Officer. “I’m very excited about the future ahead, with the opportunities that we have, including a robust pipeline, where we expect two data readouts across our hepatitis B and hepatitis D programs in 2023. We also have a strong balance sheet with approximately $1.9 billion in cash and investments, as of the end of the second quarter, which will allow us to invest in our ongoing development and future innovation.”

The Company plans to host a Second Quarter 2023 Results conference call on Thursday, Aug. 3, during which these results will be discussed.

Efficacy Analyses
Occurrence of Influenza-Like-Illness (ILI) with PCR-Confirmed Influenza A

	# of Participants with Endpoint/ VIR-2482 vs. Placebo	Placebo N = 983 n (%)	VIR-2482 450 mg N = 981 n (%)	VIR-2482 1,200 mg N = 992 n (%)
Primary Endpoint	Number of Participants Protocol-Defined ILI[1]	25 (2.54%)	24 (2.45%)	21 (2.12%)
	Relative Risk Reduction (%)	-	3.78%	15.85%
	95% CI (%)	-	-67.23, 44.63	-49.27, 52.56
	p-value	-	0.89	0.56
Secondary Endpoints	Number of Participants with CDC-Defined ILI[2]	17 (1.73%)	15 (1.53%)	7 (0.71%)
	Relative Risk Reduction (%)	-	11.45%	57.23%
	95% CI (%)	-	-76.25, 55.51	-2.51, 82.15
	Number of Participants with WHO-Defined ILI[3]	11 (1.12%)	12 (1.22%)	6 (0.60%)
	Relative Risk Reduction (%)	-	-9.80%	44.13%
	95% CI (%)	-	-147.41, 51.27	-50.49, 79.26

Note: Percentages are calculated relative to the number of participants in the full analysis set.

[1] Protocol-defined ILI is defined as PCR-confirmed influenza A infection with at least one respiratory symptom: sore throat, cough, sputum production, wheezing, or difficulty breathing and at least one systemic symptom: fever (temperature >37.8°C), chills, weakness, or myalgias.

[2] CDC-ILI is defined as fever (temperature >37.8°C) and cough and/or sore throat.

[3] WHO-ILI is defined as fever (temperature >38°C) and cough.

The PENINSULA trial has been supported in whole or 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.

About VIR-2482
VIR-2482 is an investigational hemagglutinin targeting, 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 flu pandemic. VIR-2482 is designed as a prophylactic for influenza A. It has the potential to address the limitations of current flu vaccines 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 that a single dose has the potential to last the entire flu season. Under the collaboration agreement signed with GSK in 2021, GSK has an exclusive option to lead post-Phase 2 development and commercialization of VIR-2482.

About VIR-2981
VIR-2981 is an investigational neuraminidase-targeting monoclonal antibody against influenza viruses. It targets a region of the neuraminidase protein that is highly conserved across influenza A and B strains and is designed to inhibit the influenza neuraminidase, a key viral protein that facilitates release of new viruses in infected individuals. Preclinical data demonstrate the antibody's breadth and potency against all major strains of seasonal and pandemic influenza viruses and support the potential of this antibody in the prevention of influenza illness.

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 hepatitis B and D viruses, influenza A, human immunodeficiency virus and COVID-19. 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 influenza A illness; the potential benefits of VIR-2981; the expected timing of two data readouts across Vir's hepatitis B and hepatitis D programs; Vir's cash balance, Vir's future financial and operating results and its expectations related thereto; statements regarding Vir's scientific and executional expertise, and risks and uncertainties associated with drug development and commercialization. Many factors may cause differences between current expectations and actual results, including the occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; 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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