

Pfizer to Acquire ReViral and Its Respiratory Syncytial Virus Therapeutic Candidates

Thursday, April 07, 2022 - 06:45am

.q4default .bwalignc { text-align: center; list-style-position: inside }.q4default .bwlistdisc { list-style-type: disc }

Proposed acquisition strengthens Pfizer's capabilities in infectious disease research and development with a complementary strategy to help improve patient outcomes through treatment for respiratory syncytial virus (RSV) infections and prevent illness through vaccination Expands Pfizer's innovative anti-infective pipeline and utilizes the company's R&D, manufacturing and commercialization expertise with the goal of addressing a significant unmet need for RSV treatments

NEW YORK & LONDON & RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) and ReViral Ltd. announced today that the companies have entered into a definitive agreement under which Pfizer will acquire ReViral, a privately held, clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing novel antiviral therapeutics that target respiratory syncytial virus (RSV).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20220407005230/en/

"At Pfizer, we have a strong heritage in, and commitment to, fighting infectious diseases, most recently evidenced by our delivery of the first authorized vaccine and oral therapy to combat COVID-19," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "We're continuing to grow our pipeline – through our own research-and-development efforts, such as our investigational RSV vaccine programs, as well as strategic investments in companies like ReViral – with a focus on end-to-end capabilities to help protect patients from severe illness, hospitalization, and death."

RSV is a respiratory pathogen, which can lead to severe and life-threatening lower respiratory tract infections (LRTIs) in high-risk populations, including young infants, immunocompromised individuals, and older adults. It is estimated to cause infections in approximately 64 million people, resulting in about 160,000 deaths, globally each year.

ReViral has a portfolio of promising therapeutic candidates, including sisunatovir, an orally administered inhibitor designed to block fusion of the RSV virus to the host cell. Sisunatovir significantly reduced viral load in a phase 2 RSV human challenge study in healthy adults and is currently in phase 2 clinical development in infants. The development program for sisunatovir is expected to continue in both adult and pediatric populations. A second program is focused on the inhibition of RSV replication targeting the viral N protein. The lead candidate in this program is currently in phase 1 clinical development.

"Currently, treatment options for RSV are extremely limited and focus primarily on supportive care," said Annaliesa Anderson, Ph.D., Senior Vice President and Chief Scientific Officer, Bacterial Vaccines and Hospital, at Pfizer. "The proposed acquisition of ReViral's pipeline of therapeutic candidates is complementary to our efforts to advance the first vaccine candidate to help protect against this harmful disease. Combining the capabilities and expertise of our organizations will enable us to further the clinical development of a potential therapy for those with RSV disease."

Sisunatovir has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA). In June 2021, ReViral announced the successful completion of Part A of the phase 2 REVIRAL1 study of sisunatovir for the treatment of RSV infections in hospitalized infants. REVIRAL1 is a global three-part adaptive study to evaluate the safety, tolerability, pharmacokinetic (PK) profile, antiviral effects, and clinical effect of single and multiple oral doses of sisunatovir in otherwise healthy infants between the ages of 1 and 36 months hospitalized with RSV LRTIs. Following a thorough review by the REVIRAL1 Data Safety Monitoring Committee, sisunatovir showed a favorable safety and PK exposure profile to advance to Part B, the double-blind, placebo-controlled stage of the study where patients receive drug or placebo twice a day for five days.

"Since the foundation of the company a decade ago by Dr. Ken Powell and Dr. Stuart Cockerill, ReViral's mission has always been to develop world-class therapies for RSV patients," said Alex C. Sapir, CEO, ReViral. "This acquisition represents a validation of the deep antiviral experience of the ReViral team and our unwavering commitment to deliver therapies for patients in need. Pfizer is an optimal partner given their commitment to RSV through their ongoing RSV vaccine program, coupled with their world-class clinical,

regulatory, manufacturing and commercial capabilities. We look forward to working with our colleagues at Pfizer to bring these therapies to patients as quickly as possible."

Under the terms of the agreement, Pfizer will acquire ReViral for a total consideration of up to \$525 million, including upfront and development milestones. If successful, Pfizer believes annual revenue for these programs has the potential to reach or exceed \$1.5 billion. The proposed transaction is subject to customary closing conditions, including receipt of regulatory approvals.

Clifford Chance LLP is acting as Pfizer's legal advisor. Centerview Partners LLC and BofA Securities served as ReViral's financial advisors, with Goodwin Procter LLP acting as its legal advisor.

About ReViral

ReViral is a clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing antiviral therapeutics, with an initial focus on treating respiratory syncytial virus (RSV). The company's lead product candidate, sisunatovir, is an orally administered fusion inhibitor currently being evaluated in a global phase 2 pediatric clinical study (REVIRAL1). The company also has an RSV N-protein replication inhibitor program currently in phase 1 clinical development.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice

The information contained in this statement is as of April 7, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this statement as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's proposed acquisition of ReViral, ReViral's pipeline portfolio of therapeutic candidates, including sisunatovir, and potential revenue, and Pfizer's infectious disease research and development and innovative anti-infective and vaccine portfolio and pipeline, including Pfizer's investigational RSV vaccine programs, including their potential benefits, that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, risks related to the satisfaction or waiver of the conditions to closing the proposed acquisition (including the failure to obtain necessary regulatory approvals) in the anticipated timeframe or at all, including the possibility that the proposed acquisition does not close; the possibility that competing offers may be made; risks related to the ability to realize the anticipated benefits of the proposed acquisition, including the possibility that the expected benefits from the acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the transaction making it more difficult to maintain business and operational relationships; negative effects of this announcement or the consummation of the proposed acquisition on the market price of Pfizer's common stock and/or operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition or ReViral's business; other business effects and uncertainties, including the effects of industry, market, business, economic, political or regulatory conditions; future exchange and interest rates; changes in tax and other laws, regulations, rates and policies; future business combinations or disposals; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when drug or biologic license applications may be filed in any jurisdictions for sisunatovir, Pfizer's investigational RSV vaccine or any other investigational products; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its

known risks and determination of the product's efficacy and, if approved, whether sisunatovir, Pfizer's investigational RSV vaccine or any such other products will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of sisunatovir, Pfizer's investigational RSV vaccine or any such other products; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities regarding Pfizer's investigational RSV vaccine and uncertainties regarding the commercial impact of any such recommendations; uncertainties regarding the impact of COVID-19; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

Category: Investments

View source version on businesswire.com:

https://www.businesswire.com/news/home/20220407005230/en/

Pfizer Contacts:

Media Relations +1 (212) 733-1226 PfizerMediaRelations@pfizer.com

Investor Relations +1 (212) 733-4848 IR@pfizer.com

ReViral Contacts:

Media Relations Deborah Cockerill / Jasmin Shearan / Darya Shulakova Sciad Communications Ltd +44 (0)20 3405 7892 ReViral@sciad.com

Investor Relations Alan Musso, CFO +1 (832) 270-5447 amusso@reviral.com

Source: Pfizer Inc.