

# Vir Biotechnology Proceeding with Two Clinical Development Candidates for COVID-19

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- Multiple antibodies identified that neutralize SARS-CoV-2

- Phase 1/2 clinical testing planned for this summer

SAN FRANCISCO, March 25, 2020 (GLOBE NEWSWIRE) -- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced that it has identified multiple human monoclonal antibody (mAb) development candidates that neutralize SARS-CoV-2, the virus responsible for COVID-19.

"We are pleased with the rapidity of our progress and excited to move two development candidates into human testing as soon as possible," said George Scangos, Ph.D., CEO, Vir. "Stopping this disease will take a combination of prevention and treatment approaches. At Vir, we are fortunate that our existing antibody platform gave us a running start against COVID-19, and we have the internal and partnered capabilities to work on multiple approaches."

In an effort to save time, Vir's lead development candidate was transferred at-risk to WuXi Biologics (stock code: 2269.HK) and Biogen Inc. (Nasdaq: BIIB) several weeks ago, and Vir anticipates that human trials can begin within 3-5 months. The ability of this antibody to neutralize the SARS-CoV-2 live virus has been confirmed in two separate laboratories. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (also known as SARS), indicating that the epitope is highly conserved. Vir believes that the conservation of this epitope will make it more difficult for escape mutants to develop.

Vir has engineered the Fc region of our lead development candidate in the following ways:

- 1. A half-life extending alteration to potentially extend the time over which the antibody provides protection; and
- 2. A second alteration ("vaccinal" mutation) that increases short-term potency, and in animal models leads to the generation of protective CD8+ T cells that may provide long-term immunity. This alteration gives the antibody the potential to function prophylactically, therapeutically, and to be able to induce long-term immunity (i.e., to function both as a therapeutic and a vaccine).

The lead development candidate is being produced with and without the vaccinal mutation, and Vir intends to move both versions into human testing. In addition, Vir has identified additional antibodies that bind to different sites, and therefore have the potential to be used in combination with the lead development candidate.

The company is continuing its search for additional antibodies from survivors of SARS-CoV-2, SARS-CoV-1, and other coronaviruses. These antibodies may also be candidates to address the ongoing COVID-19 pandemic as well as coronavirus outbreaks that may occur in the future. Vir's long-term goal is to identify pan-coronavirus antibodies that could be effective against most or all coronavirus outbreaks. Vir has used this same approach in the discovery and development of VIR-2482, a pan-influenza A antibody that the company is developing for the prevention of influenza A.

"We are rapidly progressing our anti-SARS-CoV-2 antibody program, including building the necessary infrastructure and partnerships to proceed with clinical development and manufacturing this year," said Herbert "Skip" Virgin, M.D., Ph.D., Chief Scientific Officer, Vir. "We expect to continuously generate data on these and additional high-priority antibodies, as well as from our efforts leveraging our siRNA and Innate Immunity platforms, until the COVID-19 pandemic is addressed."

How Antibodies Might be Used Against Coronaviruses

Vir intends to examine the potential applicability of its antibodies in four use cases:

- Prevention of disease: prophylaxis in health care workers or other individuals at high risk of becoming infected as well as prophylaxis for those at high risk of severe disease or death, such as the elderly with co-morbidities
- Prevention of progression to severe disease: treatment of SARS-CoV-2 infected patients during the early phases of infection prior to onset of severe respiratory distress
- Treatment of severe disease: treatment of SARS-CoV-2 infected patients with severe respiratory distress or other systemic illnesses
- Development of vaccines: understanding the epitopes that lead to effective neutralization can aid in the development of effective vaccines

## Multiple Programs Targeting Coronaviruses

Vir is taking multiple approaches to identify additional potential therapies for SARS-CoV-2. In addition to antibodies, the company is working with Alnylam Pharmaceuticals (Nasdaq: ALNY) to develop potential RNAi therapeutics and using its Innate Immunity Platform that applies cutting-edge genomic technologies to explore ways to interrupt the disease process using small molecules.

#### **About Vir's Antibody Platform**

Vir has a robust method for capitalizing on unusually successful immune responses naturally occurring in people who are protected from, or have

recovered from, infectious diseases. The platform is used to identify rare antibodies from survivors that have the potential to treat and prevent rapidly evolving and/or previously untreatable pathogens via direct pathogen neutralization and immune system stimulation. Vir engineers the fully human antibodies that it discovers to enhance their therapeutic potential. This platform has been used to identify and develop antibodies for pathogens including Ebola (mAb114, currently in use in the Democratic Republic of Congo), hepatitis B virus, influenza A, malaria, and others.

### About VIR-2482

VIR-2482 is an 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 prophylaxis 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 has been half-life engineered so that a single dose has the potential to last the entire flu season, which is typically five to six months long.

#### **About Vir Biotechnology**

Vir Biotechnology is a clinical-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 five product candidates targeting hepatitis B virus, influenza A, human immunodeficiency virus, and tuberculosis. For more information, please visit <a href="https://www.vir.bio">www.vir.bio</a>.

#### **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," "could," "expect," "plan," "anticipate," "believe," "estimate," "goal," "intend," "potential," "candidate," "continuing," "developing" 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. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding the timing of commencement of clinical trials of the company's antibodies to treat and prevent COVID-19, the ability of the company's antibodies to neutralize the SARS-CoV-2 virus, the company's efforts to identify additional antibodies, the timing of manufacturing a product candidate to treat COVID-19, the potential benefits of the company's collaborations with Wuxi Biologics, Biogen and Alnylam Pharmaceuticals, and the company's ability to address the COVID-19 pandemic. 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 neutralizing SARS-CoV-2, difficulty in collaborating with other companies or government agencies, and challenges in accessing manufacturing capacity. 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 ref

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