BREAKTHROUGH PROGRAM

SaudiBI

Founder

Hani Alothaid, PhD, FIBMS
Al-Baha University

Co-Founder

Reid Rubsamen, MD, MS, MHCM
CEO, Flow Pharma Inc.

Team Members

Julie Lang, MD
Cleveland Clinic

M. Alshehri, PhD
Al-Baha University

Ahmed Alqahtani, PhD
KFSHRC

Startup Brief

The long-term health, economic, and societal implications of long-COVID-19 are significant, and there is an obvious need to develop therapies to address and reduce the morbidity of this disease. However, no such therapies exist. FlowVax COVID-19 immunotherapy (FLOVID-20) works by teaching the patient's immune system to attack and kill virally-infected cells, clearing infected cells in patients with Long Haul COVID potentially curing them. The patented FlowVax platform uses tiny beads called microspheres—the same size as white blood cells—containing small protein fragments (peptides) of the COVID-19 virus. Once inside the body, these microspheres are collected by the cells of the immune system called macrophages. The FlowVax microsphere vaccine is 100% synthetic, does not contain animal products, and can be given as a single injection without requiring an intravenous infusion. This four-year proposal takes the FlowVax immunotherapy through initial Phase 1 safety trials to Phase 2 efficacy trials in human patients with recurrent or persistent COVD-19 infection (i.e., long COVID). FLOVID-20 adjuvanted microsphere peptide vaccine doses sufficient to conduct Phase 1 and Phase 2 clinical testing have already been manufactured under GMP conditions in the United States. A special diluent is used to suspend the microspheres prior to administration by intramuscular injection. A Phase 1 clinical trial has already been approved to begin in Australia and subjects can be enrolled as soon as a GLP animal safety study is completed in Columbus, Ohio. The results from this Phase 1 study will enable IND filings in the US and Saudi Arabia to begin Phase 2 testing of FLOVID-20 in Saudi Arabia to treat patients with Persistent/Recurrent COVID-19 infections.

Problem

The Centers for Disease Control and Prevention estimate that 1 in 13 adults in the United States have long-COVID-19 symptoms, defined as new symptoms lasting three or more months after first contracting the virus. As of May 2022, over 525 million confirmed cases of COVID-19 disease were reported worldwide of which one in seven remained symptomatic at 12 weeks. This suggests that the number of "long haulers," or patients with persistent/recurrent infection with SARS-CoV-2 is considerable. There are currently no agreed upon treatments for "long COVID."

The development of new treatments for this condition is hampered by the fact that new variants are appearing with increasing frequency making antibody treatments directed towards the spike protein ineffective. FLOVID-20 causes the immune system to attach the nucleocapsid protein at sites that have not mutated since the first appearance of the SARS-CoV-2 virus. The fact that these sites are also present unchanged on SARS-1 further suggests that FLOVID-20 will be effective against all future variants as well.

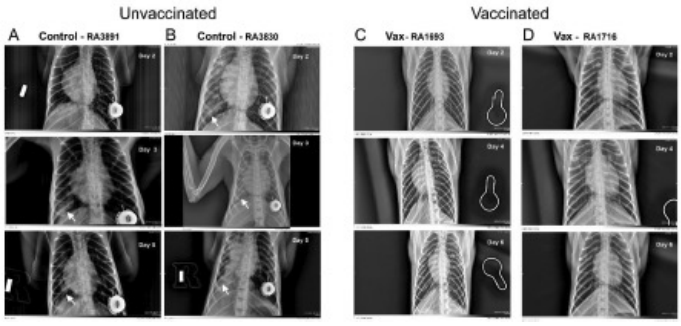

Figure 1. Representative chest radiographs of control and vaccinated macaques following SARS-CoV-2 challenge. As shown, control macaques (left columns A and B) demonstrated a progression of pulmonary infiltrates during the acute period (Days 2-5) of disease post-challenge. In contrast, vaccinated macaques (right columns C and D) lacked similar abnormalities. White arrows indicate areas of mild to moderate pulmonary infiltrates seen as ground glass consolidations (1).

Solution

Samples of FLOVID-20 for animal and human testing have already been manufactured. Flow Pharma has shown efficacy of FLOVID-20 in Rhesus Macaque animal study conducted at the US National Laboratory at Galveston Texas and these results were published in a peer reviewed journal. Flow Pharma has secured approval to test these samples in a human clinical trial which will be funded by this proposal. Patents are pending with national phase filings completed which include filings in the Kingdom of Saudi Arabia. FLOVID-20 is at TRL- 7 and will progress to TRL 9 by the end of this proposal. The FlowVax vaccine technology is currently at TRL 7. The current TRL level includes having already manufactured and tested FlowVax vaccines (including the FlowVax COVID-19 vaccine) in laboratory animals, having published efficacy results in peer reviewed journals, and having obtained issued patents protecting the FlowVax vaccine technology. The goal of this proposal is to advance the FlowVax vaccine technology to TRL 9. This will include testing FLOVID-20 immunotherapy in Phase 1 and Phase 2 clinical testing and qualifying the manufacturing process for making the FLOVID-20 on manufacturing equipment being purchased and installed in Riyadh, Saudi Arabia as part of this TBG proposal.

Value Proposition

Persistent/Recurrent SARS-CoV-2 infection (long COVID) can be a debilitating condition taking people out of the workforce and even making it difficult for them to care for themselves. Billions of dollars were spent on manufacturing and stockpiling therapeutic antibodies, however mutations in the spike protein has rendered all of those treatments ineffective. The only marketed antiviral in the US is Paxlovid which has only been shown effective during the acute phase of SARS-CoV-2 infection. A solution for long COVID would bring much needed relief to the many patients afflicted with that condition and also reduce the strain on the healthcare system and the lost productivity and the resulting economic impact. The retail price for PAXLOVID (without insurance) varies from $1,200 - $1,600 USD for a five-day course of therapy. If we price the required single injection at $1000 USD / dose and assume 10% TAM penetration at launch and define TAM as 10% of the estimated 1% of US adults with long haul (TAM = 300,000), we could achieve $300,000,000 gross revenue for the first year.

About the Research

(1) Harris PE, Brasel T, Massey C, Herst CV, Burkholz S, Lloyd P, Blankenberg T, Bey TM, Carback R, Hodge T, Ciotlos S, Wang L, Comer JE, Rubsamen RM. A Synthetic Peptide CTL Vaccine Targeting Nucleocapsid Confers Protection from SARS-CoV-2 Challenge in Rhesus Macaques. Vaccines (Basel). 2021 May 18;9(5):520