Immunovative Therapies and Mirror Biologics Announce US FDA Clearance of a Universal Anti-Viral Vaccine Phase I/II Clinical Trial for Healthy Elderly Adults

The universal vaccine is designed to protect elderly adults from all respiratory viral infections, including COVID-19, influenza and any future mutations or novel viral outbreaks.

Jerusalem and Phoenix, AZ, June 23, 2021 --(PRNewswire)-- Mirror Biologics, Inc. (Phoenix, AZ), the commercial development arm of Immunovative Therapies, Ltd. (Jerusalem, IL) (together "the Company"), a clinical-stage company specialized in the development, manufacturing and clinical translation of next-generation immunotherapy drugs where the active ingredients are living immune cells, today announced that the U.S. Food and Drug Administration (FDA) has cleared our Phase I/II universal virus vaccine clinical trial under the Company's second active Investigational New Drug (IND) application enabling use of the Company's lead experimental drug, AlloStim®, for testing as an anti-viral prophylaxis drug.

AlloStim® is an off-the-shelf, non-genetically manipulated, patented living immune cell with multiple immunodulatory properties, currently being tested under a separate IND as a therapeutic vaccine for chemotherapy-refractory metastatic cancers.

This Phase I/II trial is believed to be the first anti-viral vaccine in clinical development that is specifically targeted to protect the elderly. The elderly are the most vulnerable in our society to the severe and lethal effects of respiratory viral infections which cause disease complications such as pneumonia. Pneumonia is the single most common cause of death from infectious disease in those over 65 years old. The chance that a COVID-19 patient will develop symptoms severe enough to require hospitalization and respiratory support rises sharply with age and the death rate due to COVID-19 is disproportionately higher in our senior citizens.

Dr. Michael Har-Noy, founder and CEO stated: "We are pleased to have FDA clearance of our novel universal viral vaccine clinical trial targeted to healthy adults over 65 years old. There is a large unmet need to protect the elderly from the devastating effects of respiratory viral infection. If we can protect the elderly from COVID-19, economies can open safely and herd immunity can be allowed to develop without an alarming increase in death rate. Even if a COVID-19 vaccine is developed, it is likely, as with influenza vaccines, that it will be less effective in the elderly where protection is most needed. In addition, a successful COVID-19 vaccine is vulnerable to weakening upon mutation of the virus and will not protect against future novel viral outbreaks. Our universal vaccine technology is designed to protect against any

type of viral infection without the requirement to have prior knowledge of the viral structure and is specifically designed to work in the weakened senescent immune systems of the elderly and frail."

The Phase I/II clinical trial will accrue 40 healthy adults over age 65. Volunteers will receive five (5) intradermal injections of AlloStim® over 14 days. Blood samples will be collected prior to injection and at 30 days, 6 months and 1 year after injection. The blood will be challenged in the laboratory with a panel of live viruses, including the COVID-19 virus and influenza viruses in order to determine if the remodeled immune system can suppress the propagation of these viruses in cultures of human endothelial cells from the respiratory tract.

Details of the clinical trial can be found on the National Institutes of Health ClinicalTrials.gov registry:
ClinicalTrials.gov Identifier: NCT04441047

The universal viral protection mechanism has been reversed engineered from the immune response that results in asymptomatic viral clearance in youthful individuals. Using a novel, patent-pending technology called "allo-priming", the youthful immune response is imprinted upon the elderly immune system so that it can be ready to be activated upon encounter with any virus. The mechanism creates conditions for an "in-situ" vaccine providing viral-specific protection and memory to prevent re-infection from the same virus. The novel mechanism has been described in a peer-reviewed article published in the Journal of Translational Medicine which can be viewed by following this link.

AlloStim® is derived from precursor cells purified from the blood of healthy donors. The Company will be working to scale up and automate the production process in parallel with on-going clinical trials so that upon demonstration of safety and efficacy, the vaccine can be quickly scaled-up to quantities necessary to protect the elderly population. Today, there is estimated to be more than 46 million adults age 65 and older living in the USA.

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