



Mirror Biologics, Inc. Announces Initiation of AlloStim® Phase I/II Universal Viral Vaccine Clinical Trial (ALLOPRIME) in Healthy Adults Over 65 Years Old

Tampa, FL, July 14, 2021 --([PR.com](#)) -- Mirror Biologics, Inc. ("Mirror Biologics" or the "Company"), a clinical stage immunotherapy company specializing in the development, manufacturing and clinical translation of next generation therapeutic in-situ vaccines for cancer and infectious diseases where the active ingredients are living immune cells, announced today the initiation of the ALLOPRIME universal viral vaccine Phase I/II clinical trial (ClinicalTrials.gov ID: NCT04441047). The study tests whether priming with the immunotherapy drug AlloStim® will provide greater immune protection for the elderly from serious disease resulting from any type of respiratory viral infection, including COVID-19 and all variants, and any future virus that may become pandemic. The study is being conducted at the Florida Medical Clinic in Zephyrhills, Florida which is now accepting healthy volunteers over 65 years old. Dr. David Sikes, MD is serving as the Principal Investigator of the study. Volunteers are eligible even if they have been previously vaccinated against COVID-19 and unvaccinated volunteers are eligible for a COVID-19 vaccine 30 days after receiving the AlloStim® dosing.

Respiratory viral infections, such as COVID-19, RSV (respiratory syncytial virus) and influenza A/B, disproportionately affect the elderly. A young healthy person exposed to these viruses generally only develops a very mild disease, while the same infection in the elderly often leads to pneumonia requiring hospitalization (called Community Acquired Pneumonia or "CAP"). CAP in elderly often progresses to serious breathing problems and sepsis which is often lethal in the elderly. This Phase I/II study is investigating a new immunomodulatory vaccine concept called "AlloPriming," previously described in the *Journal of Translational Medicine*, which is designed to protect the elderly from serious disease and hospitalization upon viral infection and CAP.

CAP is one of the most common and morbid conditions encountered in clinical practice. In the United States, CAP accounts for over 4.5 million outpatient and emergency room visits annually. CAP is the second most common cause of hospitalization and the most common infectious cause of death. There are approximately 1.5 million adults that are hospitalized each year in the United States due to CAP. Nearly 9 percent of patients hospitalized with CAP will be re-hospitalized due to a new episode of CAP during the same year.

The study will evaluate 40 total subjects (20 subjects between 65-74 years old and 20 subjects over 75 years old). Blood samples will be drawn prior to vaccination and at various times after vaccination to



determine the duration of any protective effect. The blood will be analyzed in the laboratory for its ability to protect against various viral infections of human cells lining the lung.

Adi Raviv, CEO of Mirror Biologics stated, “Our AlloPrime universal vaccine technology was developed by analyzing data obtained in our on-going therapeutic cancer vaccine clinical trial programs. In theory, if we are successful in modulating the elderly immune system in such a manner that the response to a virus infection 'mirrors' the response to a virus of a healthy younger person, this new kind of vaccination strategy could potentially provide the elderly with greater protection from the serious consequences of viral infections that progress to CAP. Moreover, the unique aspect of this next generation vaccine technology is that it might be possible to provide greater immune protection against known and unknown viruses without the requirement to have prior knowledge of the type of virus or the genetic make-up of the virus. We hope that this technology might become part of a National healthcare strategy to keep the immune systems of the elderly strong, thereby providing greater protection against any future pandemic viral infections.”

Avi Kamelhar, the CEO of Axella Research, which is managing the AlloPrime study, stated: “Axella Research is very pleased to have been selected by Mirror Biologics to provide clinical research management services for the AlloPrime Phase I/II clinical trial. CAP is the leading cause of death among infectious diseases and remains an important health problem. This clinical trial focuses on protecting the elderly which are the most vulnerable to CAP. Mortality remains very high in severely ill patients presenting with respiratory failure or shock due to respiratory viral disease. Even after a CAP episode, there remains a higher risk of death, a risk mainly driven by inflammation and patient-related co-morbidities. Axella is honored to collaborate to investigate new approaches to protect the elderly from CAP. If the AlloPrime mechanism can be proven, it could potentially save many lives as well as reduce the enormous economic burden of CAP on society and the healthcare system.”

About Mirror Biologics

Mirror Biologics is an international biopharmaceutical company founded in 2019 and is headquartered in Tampa, Florida where it conducts advanced bioengineering research and development and is establishing a 21 CFR 1271-compliant blood donor and cell processing center. Mirror Biologics operates a GMP cell manufacturing facility in Jerusalem, Israel and has clinical and distribution partner offices in Bangkok, Thailand and Kuala Lumpur, Malaysia. The Mirror Effect technology platform is protected by over 200 patents issued worldwide. The lead drug, AlloStim®, is an “off-the-shelf,” non-genetically manipulated, patented, living immune cell differentiated from precursor cells purified from blood of healthy donors and formulated with monoclonal antibody-coated microparticles. The unique feature of AlloStim®



is that can imprint a protective or therapeutic cellular immune response that is customized to a patient's resident disease without need to have prior knowledge of the type of cancer/virus or genetic properties of the disease. Proprietary "artificial lymph node" bioreactors are expected to enable the economical high cell density scale-up of AlloStim®. Novel frozen dosage forms of AlloStim® enable extended shelf life and economical wide-scale distribution capability. Mirror purchased the exclusive, worldwide rights to AlloStim® and the Mirror Effect technology platform from Immunovative Therapies, Ltd, an Israeli company.

For more information on Mirror Biologics technology visit our website: www.mirrorbio.com

Forward-Looking Statements

The information contained herein may contain "forward-looking statements." Forward-looking statements reflect the current view about future events. When used in this press release, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan," or the negative of these terms and similar expressions, as they relate to us or our management, identify forward-looking statements. Such statements include, but are not limited to, statements contained in this press release relating to the view of management of Mirror Biologics concerning the development of its products, its business strategy, future clinical trials, operating results, liquidity and outlook for capital resources. Forward-looking statements are based on the Company's current expectations and assumptions regarding its business (including the course of its drug development and clinical trials), the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. The Company's actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Factors or events that could cause the Company's actual results to differ may emerge from time to time, and it is not possible for the Company to predict all of them. The Company cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

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