# Mirror Biologics Announces Issuance of US Patent Covering Next Generation Therapeutic Vaccine Technology for Treatment of Cancer and Infectious Disease

Tampa, FL, November 17, 2021 --(PR.com)-- Mirror Biologics, Inc., a private clinical stage biopharmaceutical company, today announces the issuance of US Patent No. 11,160,852, “Method of Vaccinating Using Allogeneic Cells,” covering methods for creating a next generation of therapeutic vaccines against cancers and infectious diseases. Unlike classic vaccines that are designed to protect against disease occurrence, therapeutic vaccines are designed to treat an existing disease. The unique feature of this patented technology is that it utilizes an allogeneic “off-the-shelf,” non-genetically altered, living immune cell drug called AlloStim® to elicit a powerful therapeutic immune response customized against the type of disease existing within the patient receiving treatment, regardless of the type of disease and without need for prior knowledge of the type of disease or genetic or antigenic structure of the disease.

Therapeutic vaccines are designed to educate the immune system to identify and eliminate diseased cells, such as tumors or viral infected cells. The most powerful anti-tumor and anti-viral immune responses are mediated by the cellular arm of the immune system, while protective vaccines that target the antibody arm of the immune system (e.g., current COVID-19 vaccines), have not worked well in patients with existing disease. Vaccines normally contain at least one antigen, or piece of the diseased cell or virus, and an adjuvant which is capable of promoting a cellular immune response to the selected antigen(s). The lack of unique antigens, especially for cancer, has raised significant challenges to the advancement of therapeutic vaccine strategies. Current experimental therapeutic cancer vaccines attempt to identify antigens on the surface of tumor cells that are expressed in higher quantities as compared to normal cells. The hope of therapeutic vaccine developers using this current technology is to find a particular antigen that might apply to a large proportion cells of a particular tumor type found within a patient that could also be useful for other patients with that same cancer.

The search for unique antigens has focused on surface antigens that might be over-expressed on tumor cells compared to normal cells (so called “tumor-associated antigens” or “TAA”). However, use of TAA can cause significant off-target killing of normal cells expressing the same antigen, resulting in significant toxicity. Another complication in the search for unique surface antigens is that tumor cells within a lesion, between different lesions in the same patient and lesions of the same tumor type between different individuals, do not express the same surface antigens. Further complicating this classic approach for therapeutic vaccine design is the fact that the host immune system of a patient with an existing tumor has already been exposed to the TAA surface antigens and failed to eliminate the disease. Therefore, re-

introduction of the same prior-exposed TAA would not be expected to result in a different outcome in terms of disease control. Finally, contributing to the difficulties in developing effective therapeutic vaccines is that once disease is established, it can hide from an immune response and the microenvironment around the disease is capable suppressing any effective immune response which is elicited through vaccination. This newly issued US patent solves these problems associated with the design of therapeutic vaccines.

Adi Raviv, CEO of Mirror Biologics stated, “This newly issued US patent adds to our over 200 issued patents worldwide covering our ‘Mirror Effect’ platform technology. This new patent protects our next generation, disease agnostic, therapeutic vaccine technology for cancer and infectious disease. This technology overcomes the problems of antigen selection and immune suppression which have inhibited the advancement of this type of immunotherapy. Instead of trying to select a unique common surface antigen for each targeted disease, we use the internal contents of the resident disease as the source of antigen. In other words, the vaccination step occurs within the body using the disease as the source of antigen. We also create conditions to elicit a customized cellular immune response to the released antigens. Internal antigens combined with a method to cause hidden disease to become exposed and recognized by the immune system creates a unique type of vaccination. An additional feature of this technology creates conditions to over-come the ability of the disease to suppress an effective immune response elicited by vaccination. These features, combined with our programs to develop custom bioreactors to economically mass produce and distribute AlloStim®, the active off-the-shelf living immune cell vaccine component, we believe will create a new generation of economical, widely applicable, therapeutic vaccines against many types of cancer and viral infections.”

The unique antigens of a tumor (known as “neo-antigens”) are not found on the surface of tumor cells, but rather are hidden inside the tumor cells. By causing the death of some tumor cells in a manner that causes the release of these internal neo-antigens into the microenvironment is a strategy which by-passes the need to identify unique antigens for vaccination. Tumors can be killed in a manner which stimulates an immune response (immunological cell death) by using strategies such as radiation, cryoablation, high energy ultrasound, lytic viruses, some types of chemotherapy and activation of natural killer cell activity. Since the vast majority of neo-antigens in tumors are unique to a given patient, this type of “in-situ” vaccination creates a truly personal therapy customized for each patient, yet elicited by an off-the-shelf drug without incorporating any antigen. The ability to create a disease agnostic, personalized therapy with an off-the-shelf drug is a major advantage of this patented technology.

Dr. Michael Har-Noy, the inventor of the patented next generation therapeutic vaccine technology, stated, “Inducing and stimulating an immune response specifically at the tumor site by causing immunological

cell death takes advantage of the whole repertoire of tumor neo-antigens which reside within stressed cells, such as tumors and viral infected cells, attached to chaperone proteins. Using the released chaperone proteins eliminates the need to identify and include any unique antigen(s) within the vaccine. The key aspects of this technology are a step which first involves the conditioning of the tumor micro-environment to make it highly inflammatory and full of 'danger' signals prior to an event which causes the disruption of the diseased cell membrane and the release of internal chaperoned neo-antigens. The inflammatory micro-environment into which the chaperoned neo-antigens are released serves both as an adjuvant to direct a cellular immune response and as a strategy to reverse the immunosuppressive signals. This technology has demonstrated significant reprogrammed anti-tumor immune activity in clinical trials of patients with chemotherapy-refractory metastatic solid tumors."

This patented technology represents a means to consistently elicit abscopal effects which can sometimes rarely be observed after radiation therapy, where irradiation of one metastatic lesion results in the immune elimination of a distant metastatic lesion. This technology also represents an improved method for eliciting "in-situ" vaccination compared to oncolytic viral induced methods.

**About Mirror Biologics**

Mirror is an international biopharmaceutical company founded in 2019 and is headquartered in Tampa, Florida where it conducts advanced bioengineering research and development is establishing a 21 CFR 1271-compliant blood donor and cell processing center. Mirror operates a GMP cell manufacturing facility in Jerusalem, Israel and has clinical and distribution partner offices in Bangkok, Thailand and Kuala Lumpur, Malaysia. 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. A Phase IIb clinical trial is currently accruing patients with chemotherapy-refractory metastatic colorectal cancer in the USA. A Phase II/III randomized, controlled clinical trial in advanced liver cancer is scheduled for launch in early 2022. Proprietary "artificial lymph node" bioreactors are expected to enable the economical high cell density scale-up of AlloStim® and a novel frozen dosage form enable extended shelf life and economical distribution. 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 its business strategy, future operating results and liquidity and capital resources outlook. Forward-looking statements are based on the Company's current expectations and assumptions regarding its business, 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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