Mirror Biologics, Inc. Announces Initiation of AlloStim® Phase IIB Clinical Trial (STIMVAX) in Patients with Metastatic Colorectal Cancer

Tampa, FL, July 08, 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 cancer vaccines in which the active ingredients are living immune cells, today announced initiation of the STIMVAX Phase IIB, pre-registration, open-label, multi-site, clinical trial for patients with chemotherapy-refractory (third line) and immunotherapy-refractory (MSI-S) metastatic (stage IV) colorectal cancer (CRC) (ClinicalTrials.gov ID: NCT04444622). The first subject received the first dose of the study drug, AlloStim®, on July 7, 2021. Currently, the Bruckner Oncology Clinic in Bronx, NY and the Alpha Research Institute in Houston, TX are actively recruiting patients for this study.

This Phase IIB open-label clinical study is evaluating the ability of the Company’s experimental immunomodulatory drug, AlloStim®, to extend survival while maintaining quality of life in patients with metastatic CRC that has progressed after at least two prior lines of chemotherapy (third line metastatic disease) and where the disease is characterized as microsatellite instability stable or “MSI-S” (meaning disease is refractory to other immunotherapies). Approximately 24 subjects are planned to participate in this study.

Adi Raviv, CEO of Mirror Biologics stated: “The launch of this clinical trial is starting an important next stage in the clinical development of AlloStim® as a therapeutic vaccine with the potential for helping patients suffering from metastatic CRC. Our goal is to provide not only an effective and safe therapy, but also a cost effective therapy for patients suffering from this disease. This Phase IIB clinical trial is being conducted at community oncology centers, as we envision that AlloStim® could someday be primarily administered in this type of out-patient setting. The hope is that this would provide increased access for patients suffering from later stages of metastatic CRC that is no longer responding to chemotherapy with a treatment at a significantly reduced cost.”

This late stage clinical trial program follows a positive review from the Independent Data Safety Monitoring Board (DSMB) that provided oversight of the previous AlloStim® Phase IIA dose escalation and dose finding study which was conducted at Banner-MD Anderson Medical Center in Gilbert, AZ with Dr. Madappa Kundranda, MD, PhD, Chief, Section of Medical Oncology serving as the principal investigator. The prior Phase IIA study provided the basis for the design of the current Phase IIB protocol which is designed to optimize safety while maintaining anti-tumor effects and survival trends which were

favorable as compared to historical data on currently approved treatments for third line metastatic colorectal cancer.

CRC is one of the most common cancers worldwide, with over 1.8 million new cases diagnosed annually. The United States is among the countries with the highest incidence of CRC, with an estimated 145,600 new CRC cases diagnosed each year. CRC remains the third leading cause of cancer-related mortality in the United States, where an estimated 51,000 deaths from CRC occur each year. Metastases are the main cause of CRC-related mortality. Approximately, 22% of CRCs are metastatic at initial diagnosis, and about 70% of patients will eventually develop metastatic relapse. Patients with metastatic CRC face poor prognosis in general, with a relative 5-year survival rate of only 14%.

Avi Kamelhar, CEO of Axella Research, the CRO managing the study stated: “We are very pleased to have been selected by Mirror Biologics to conduct this Phase IIB study in metastatic CRC. There is a high unmet medical need for new treatments for chemotherapy-refractory metastatic CRC, which is known not to respond to immunotherapy. Therefore, the evidence of anti-tumor activity in the prior Phase IIA clinical study is encouraging. Current treatments for third line metastatic CRC are toxic and provide only modest extension of survival. AlloStim® is being evaluated in the community oncology setting to determine if it can fill the need for an effective and safe out-patient treatment that extends life while at the same time maintaining the quality of life in the third-line setting. If successful in meeting the pre-defined end-points, this trial could serve as a basis for applying for expedited regulatory review.”

About Mirror Biologics, Inc.

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 the 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® and novel frozen dosage forms enable extended shelf life and economical distribution. Mirror Biologics 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 the Company concerning the development of its products, its business strategy, future clinical trial and operating results, and liquidity and capital resources outlook. 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 or 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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