



Mirror Biologics, Inc. Announces Initial Clearance for Phase II/III Clinical Trial (ALIVE) in Advanced Liver Cancer

Tampa, FL, September 10, 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 vaccine immunotherapy for cancer and infectious diseases where the active ingredients are living immune cells, announced today the clearance of the “ALIVE” Phase II/III randomized, controlled clinical trial for subjects with advanced, treatment-naïve, hepatocellular carcinoma (HCC) by the Malaysian Research Ethics Committee (MREC) and the Thailand Central Research Ethics Committee (CREC) (ClinicalTrials.gov ID: [NCT05033522](#)).

The ALIVE trial is evaluating AlloStim® immunotherapy in Asian patients with advanced HCC (BCLC stage C) unable to access, or not eligible for, sorafenib first line treatment and without any other prior treatment. 180 subjects will be randomized 2:1 to AlloStim® immunotherapy vs Physician's Choice of palliative chemotherapy (FOLFOX4) plus best supportive care or best supportive care alone at 9 academic and private medical center sites located in Thailand and Malaysia.

HCC is the predominant primary liver cancer and is the third most common cause of cancer-related death in the Asia-Pacific region. HCC is endemic in Asia, with 55% of all HCC cases worldwide reported from China. Significant differences exist between Eastern and Western populations on many key aspects of HCC, contributing to different treatment outcomes. Eastern populations tend to have worse prognosis and shorter life expectancy than Western populations. The worse prognosis is related to high incidence of chronic hepatitis B virus infection, which is the major cause in of HCC in Asia-Pacific countries.

ClinActis Pte. Ltd., a CRO specialized in managing clinical trials in the Asia-Pacific region, was appointed to manage the ALIVE trial. Christophe Tournier, MD, the CEO of ClinActis, stated: “The ALIVE trial is specifically designed to address the ‘real-life’ situation for treatment of advanced HCC in SE Asia. Many patients initially present with advanced disease when treatment options are limited. In most Asian countries, sorafenib is largely accepted as the standard of care, but availability and use are limited by cost and toxicity, resulting in the majority of advanced HCC cancer patients being provided only supportive care. A subset of these patients are provided palliative FOLFOX4 chemotherapy, which is an accepted treatment option under East Asian Guidelines for patients unable to obtain access to sorafenib. The ALIVE study is powered to detect a 40% or greater difference in overall survival between AlloStim® and the standard of care for most patients in SE Asia.”



Adi Raviv, CEO of Mirror Biologics stated: "This will be the first randomized, controlled study for AlloStim®. This study design is the gold standard for clinical evaluation of oncology drugs. Our earlier Phase IIA clinical study in advanced liver cancer conducted at Khon Kaen University Medical Center in Thailand reported 5 of 15 subjects living over 1 year compared to 4.2 months (range: 3.75-5.46 months) life expectancy reported in the placebo arm of the Asian-Pacific sorafenib historical control study for this population. It is our hope that the ALIVE trial will provide evidence of statistically significant extension of survival, while maintaining quality of life, and upon achieving such evidence we will seek to obtain regulatory approval to provide patients in the region a new affordable treatment option."

The ALIVE trial is expected to launch in early 2022. The lead principal investigator for the ALIVE study in Malaysia, Dr. Kanathan a/l Ratnavelu, of Nilai Medical Center stated, "Our group has had previous experience in providing AlloStim® on a compassionate basis to some of our chemotherapy-refractory metastatic cancer patients. In these trials, AlloStim® was well tolerated and provided benefit to some of these terminally-ill patients that had exhausted all available treatments. There is a great unmet medical need in Asia for effective, low cost and non-toxic treatment options for patients with advanced liver cancer. We are looking forward to participating in the ALIVE study with our colleagues in Malaysia and Thailand to evaluate whether AlloStim® can qualify as a first-line treatment option for advanced HCC in SE Asia."

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 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 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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