



## **Mirror Biologics Announces Appointment of Global CRO Parexel to provide Regulatory & Access Consulting services**

Tampa, FL, August 2, 2021 - Mirror Biologics, Inc. ("Mirror" 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, today announced plans for the next phase of development for its experimental drug AlloStim®. AlloStim® is an "off-the-shelf" living immune cell therapy based on the patented Mirror Effect® platform protected by over 200 issued patents. AlloStim® elicits a variety of immunomodulatory and immunostimulatory properties that can be integrated into specially designed protocols to elicit the 'Mirror' of proven immune cascades and imprint them upon a failed immune response.

Our cancer protocols aim to 'mirror' the beneficial anti-tumor effects that occur after allogeneic stem cell transplant procedures while eliminating the GVHD side effects, requirement for a matched tissue donor or need for chemotherapy conditioning. Our Universal Respiratory virus vaccine protocols intend to 'mirror' the beneficial immune response of young healthy adults and imprint this response upon the elderly.

Mirror has two active Investigational New Drug (IND) applications in the USA and one in SE Asia evaluating the safety and efficacy of AlloStim®. In the USA, one IND is active for metastatic cancer indications and a second IND is active for viral prophylaxis (protection from infectious viral infections). The first, a Phase IIB pre-registration open label, multi-site study has been initiated in third line metastatic colorectal cancer and, the second, a Phase I/II clinical trial in healthy elderly adults has been launched. This trial is evaluating the ability of AlloStim® to safely protect against multiple types of respiratory viral infections, including, but not limited to, COVID-19 (both known and unknown current and future variants), respiratory syncytial virus (RSV), influenza A and influenza B. The third, in SE Asia, where the Company is seeking regulatory clearance for a Phase II/III randomized, controlled clinical trial in 180 subjects with advanced liver cancer.

Providing Regulatory & Access Consulting services in support of the development of AlloStim® is Parexel, a leading global clinical research organization (CRO) focused on development and delivery of innovative new therapies to advance world health. Parexel's Regulatory & Access Consulting team



includes more than 1,000 experts globally, experienced in guiding customers through all aspects of the regulatory process.

“We look forward to accelerating our clinical development programs toward regulatory approval and commercialization, particularly in our complex field of advanced living immune cell therapies derived from healthy blood donors,” notes Adi Raviv, CEO of Mirror. “This collaboration strengthens our global Regulatory Affairs and allows us to expand our strategic capabilities to support our late stage clinical development programs both in the USA and in SE Asia in cancer and in our vaccine development strategy in USA and the world.”

### **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 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. Mirror purchased the exclusive, worldwide rights to AlloStim® and the Mirror Effect® technology platform from Immunovative Therapies, Ltd, an Israeli company.

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 it 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 manufacturing scale-up of AlloStim®. Also, novel frozen dosage forms enable extended shelf life and cost-effective distribution.

For more information on Mirror Biologics technology visit our website: [www.mirrorbio.com](http://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 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 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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