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New generation of therapeutic cancer vaccines affordable to the masses

Immunotherapy is now accepted as a new treatment modality for cancer. US FDA approved checkpoint blockage, anti-CTLA4 and anti-PD1/L1, monoclonal antibody drugs and autologous CAR-T cells are the first generation of drugs with an immune-mediated anti-tumor mechanism. These immunotherapy drugs have demonstrated ability to control metastatic disease and hematological malignancies. However, these first generation immunotherapy drugs work in only a limited number of indications and in only a minority subset of patients within these limited indications, particularly the small subset with tumors that express high mutational load status. In addition, these first generation drugs have unique and often serious immune-related side-effects that require intensive expert supportive care. While many patients can achieve long-term disease control with current immunotherapy drugs, the majority of patients experience only the side-effects without clinical benefit. The limited applicability and efficacy of checkpoint blockade drugs is due to the requirement for a pre-existing, effective immune response to be resident within the tumor lesions ("hot" tumors) in order for the mechanism of checkpoint blockade to be effective. The majority of human tumors lack an effective immune cell infiltrate ("cold" tumors). CAR-T cells are directed against surface antigens on tumor cells. This limits the use of this technology to hematological malignancies, as solid tumors lack unique surface antigen targets which are not expressed on normal tissues. Additionally, due to the cost of current immunotherapy drugs and the cost to treat the side-effects, the majority of the population in the developing world is unable to afford these drugs. Accordingly, there is a high unmet medical need for a broadly effective, low toxicity cancer immunotherapy drug that could be afforded by economically disadvantaged cancer patients. The immunotherapy drugs with the greatest potential for broad applicability against all types of tumors is the subclass of therapeutic cancer vaccines. This type of immunotherapy approach is designed to educate the immune system to specifically recognize tumors and thus create "hot" tumors as well as support the development of immune memory which provides long-term protection against recurrence of the targeted tumor without need for further treatment. Unfortunately, therapeutic cancer vaccines alone or in combination with checkpoint blockade have had disappointing results in the clinic. The failure of therapeutic vaccines is attributed to the multiplicity of complex immunosuppressive and immunoavoidance mechanisms employed by tumors to evade immune elimination. We have developed a new generation of therapeutic vaccines that are designed to provide non-toxic tumor debulking immunity and disease stabilization that are available in an "off-the-shelf" format that potentially can make these vaccines "affordable to the masses". This new generation therapeutic vaccine technology is based upon the proven Graft-versus-tumor (GVT) mechanism that occurs after allogeneic, non-myeloablative stem cell transplantation (ASCT) procedures. GVT has been described as the most powerful anti-tumor mechanism ever discovered as it is the only mechanism proven capable of mediating tumor debulking of chemotherapy-refractory metastatic disease. However, the clinical application is limited due to the GVT effect association with the extremely toxic and often lethal side-effect known as Graft-versus-host disease (GVHD). The separation of the beneficial GVT effect from the devastating GVHD effects is the "holy grail" of transplant research. However, the intimate and proportional relationship of these effects has not allowed successful separation. We have developed a bioengineered allograft called "AlloStim®" which has been engineered to reverse the immunological flow of the linked GVT/GVHD effects to enable the effects to emanate from the host, rather than the draft. This creates a non-toxic Host-versus-graft (HVG) rejection that is linked to a Host-versus-tumor (HVT) effect. The HVT effect is as powerful as the GVT effect of ASCT, without need for chemotherapy conditioning or matched tissue donor. Because the AlloStim allograft is derived from healthy blood donors and one donor can produce enough

cells after *ex-vivo* differentiation and expansion to treat potentially hundreds of patients, the drug provides an economy of scale that can be translated into a treatment affordable to the masses. We will be presenting clinical data demonstrating the anti-tumor effects of this next generation therapeutic vaccine in Thai patients with advanced/metastatic head and neck cancer and advanced/metastatic hepatocellular carcinoma.

Biography

Michael Har-Noy is an Immunologist and Bioengineer with over 30 years of experience in cellular immunotherapy, having developed and clinically tested unique LAK, TIL and Th1 cell therapies for cancer and HIV/AIDS as well as methods for their manufacturing under GMP. He has attended an MD-PhD program at Rush University Medical School in Chicago specializing in Immunology and Bioengineering and performed Postdoctoral work at the University of Minnesota. He did a Clinical Research Fellowship in Immunology and AIDS at Harvard University Medical School where he was appointed as an Officer. He is currently affiliated with the Department of Bone Marrow Transplantation and Cancer Immunotherapy at the Hadassah-Hebrew University Medical Center in Jerusalem. He is also the Founder and CEO of Immunovative Therapies, Ltd. He has over 200 issued patents in the field of immunotherapy and is an expert in the design and development of process control algorithms for large-scale, high density cell culture bioreactors. His passion is to develop effective, minimally toxic cancer vaccines that can be economically mass produced and distributed so that they can be affordable to patients suffering from advanced cancer in economically disadvantaged regions.

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