

Dr. Michael Har-Noy Will Test AlloVaxTM In Patients With Refractory Head And Neck Cancer

Dr. Michael Har-Noy, CEO of Immunovative Therapies, Ltd., a biotechnology company Israel, will conduct a Phase I/II trial of his proprietary compound AlloVaxTM

DENVER, CO, USA, July 18, 2014 / EINPresswire.com/ -- Dr. Michael Har-Noy, founder and CEO of Immunovative Therapies, Ltd., an Israeli biotechnology company, will be conducting a Phase I/II study of AlloVaxTM, one of his proprietary compounds, in the treatment of patients with head and neck cancer. Dr. Michael Har-Nov says the purpose of this study is to ascertain the safety and tolerability of a the individualized anti-cancer vaccine AlloVaxTM in patients with recurrent or metastatic head and neck squamous cell carcinoma of the head and neck who are not candidates for surgical, chemotherapeutic, or radiation treatment. AlloVaxTM is a personalized anti-cancer vaccine developed by Dr. <u>Michael Har-Noy</u>. It combines Chaperone Rich Cell Lysate (CRCL), a source of tumor antigen synthesized from patient's cancer cells, with AlloStimTM, a patented biologic compound developed at Immunovative Therapies, Ltd. The combination of CRCL and AlloStimTM will hopefully provide all the key components necessary to for the study patients to develop a tumor-specific immune reaction. Dr. Michael Har-Noy says that the AlloVaxTM vaccine is designed to create an extremely inflammatory environment, which is necessary for the patient's immune system to overcome the immunosuppressive environment produced by the tumor. The AlloVaxTM will hopefully break the cancer's immune tolerance, thereby providing specific head and neck cancer tumor antigens which will facilitate the production of a specific adaptive anti-tumor reaction.

Dr. Michael Har-Noy indicates that the study will be conducted in a randomized, double blinded, placebo controlled fashion. This means that both the investigators and patients will be blinded as to what treatment arm each subject will enter. All accrued subjects will undergo tumor harvest procedures. Dr. Michael Har-Noy says that the samples of tumor will then be made into personalized Chaperone Rich Cell Lysate (CRCL) vaccines for each study arm patient. The study patients will be assigned in a 3:1 ratio to either the AlloVaxTM or the placebo treatment arms. Both the study AlloVaxTM and control (placebo) patients will receive equally diligent supportive care. Dr. Michael Har-Noy indicates that for each cycle of treatment, the study arm patients will be given AlloVaxTM (intradermal administration of AlloStimTM followed immediately by the intradermal CRCL injection) weekly for three weeks followed by AlloStimTM intravenous infusion in week four. The placebo study will receive an AlloVaxTM placebo weekly for the three weeks followed by an intravenous AlloStimTM placebo infusion in week four. Dr. Michael Har-Noy

indicates that each study arms will be treated for four cycles.

Dr. Michael Har-Noy indicates that the study's primary outcome measure will be to compare the tolerability and safety of the proprietary AlloVaxTM preparation to that of the placebo. He says that the study time frame will be from the start of treatment to 30 days after the last dose (approximately five months). Dr. Michael Har-Noy says that the overall patient safety, side effects and overall tolerance of the AlloVaxTM will be ascertained by serial physical exams, laboratory tests, and symptoms reported by the study patients.

The study's secondary outcome measures, says Dr. Michael Har-Noy, will be magnitude of the study patients' anti-tumor specific immune response. This response will be evaluated 30 days after the last dose of AlloVaxTM. The radiologic and pathological changes of the anti-tumor response will also be evaluated at this time. Dr. Michael Har-Noy and his team will then track the progress of the study patients on a long-term basis.

About: Dr. Michael Har-Noy is the founder and CEO of Immunovative Therapies, Ltd. a biotechnology company in Israel. Dr. Michael Har-Noy is developing and testing unique immune-based cancer therapies that, when marketed, will likely revolutionize the field of oncology.

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