Society for Immunotherapy of Cancer

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OPTiM Trial Results are First Positive Phase 3 Oncological Virus Cancer Immunotherapy Study in Melanoma

SITC member's study pioneers new immunotherapy approach for cancer treatment

MILWAUKEE, WI – Results from the Oncovex (GM-CSF) Pivotal Trial in Melanoma (OPTiM) have been announced, finding that a genetically modified version of herpes simplex virus type 1, designated talimogene laherparepvec (T-VEC), shrank tumors of the deadly skin cancer melanoma in patients who were in the late stages of the disease.

The T-VEC virus works through direct destruction of melanoma cells and contains the gene encoding a cytokine called GM-CSF that helps to initiate an immune response against the melanoma. This is the first prospectively, randomized phase 3 clinical trial of an oncolytic virus cancer immunotherapy to demonstrate a clinical benefit in cancer patients.

The Society for Immunotherapy of Cancer Vice President, Howard Kaufman, MD was the principal investigator on the study, which was conducted in four countries around the world with several SITC members as co-investigators, including Drs. Igor Puzanov, Ernest Borden, Brendan Curti and Theodore Logan.

The study consisted of treating one group of patients with T-VEC, while the other group was treated with a control drug, GM-CSF. Sixteen percent of those who were treated with the virus saw their tumors partially or completely shrink for at least six months. This is compared to only 2% of patients from the GM-CSF group who saw their tumors shrink partially or completely.

"These results highlight the promise of vaccination as a form of cancer immunotherapy," Dr. Kaufman said.

Vaccines have been of intense interest to tumor immunologists and oncologist for many years based on the identification of tumor-associated antigens and therapeutic responses observed in animal models. The OPTiM clinical trial was designed to detect an improvement in durable responses for at least six months.

"While these results are encouraging, expected survival data should confirm the potential impact of T-VEC to improve outcomes for patients with melanoma." Dr. Kaufman added.

The positive trial result from the OPTiM study comes after the FDA approval of a vaccine for the treatment of prostate cancer (Sipeulcel-T) and several other types of cancer immunotherapy,

including cytokines (interferon-alpha and interleukin-2 for melanoma and renal cell carcinoma) and the T cell checkpoint inhibitor, ipilimumab, for advanced melanoma.

"The increasing number of immunotherapy agents demonstrating clinical benefit supports the importance of continued funding for immunotherapy research and clinical development," he continued.

To aid in this effort, the Society for Immunotherapy of Cancer is a professional medical association dedicated to supporting education, research and clinical development of immunotherapy treatment options for patients with cancer.

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