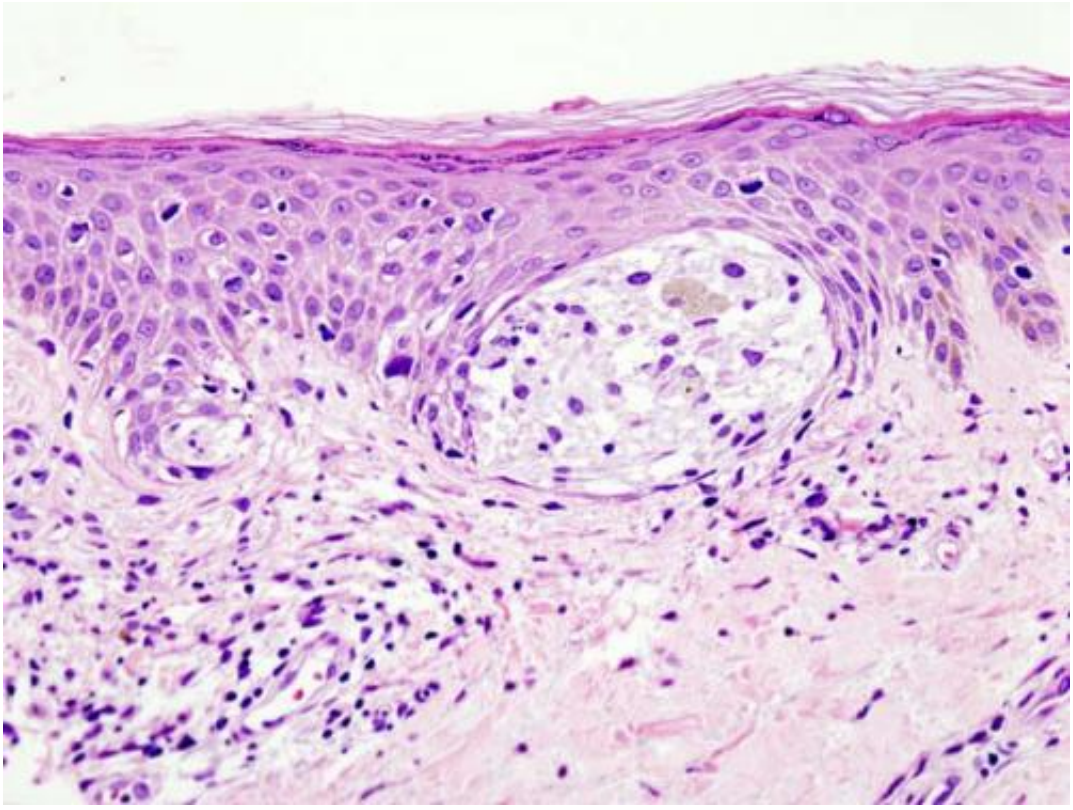
FDA approves cancer-killing cold sore virus as therapy for late-stage melanoma

October 28 2015



Melanoma in skin biopsy with H&E stain—this case may represent superficial spreading melanoma. Credit: Wikipedia/CC BY-SA 3.0

The U.S. Food and Drug Administration announced on Oct. 27 that it has approved, for the first time, an oncolytic (cancer-killing) viral therapy in the United States. The drug was approved for use against late-stage melanoma, a deadly skin cancer that can be difficult to treat.

The approval came as the result of a recent Phase III study, which showed that more patients with late-stage melanoma, treated with a herpes cold sore virus designed to kill tumor cells, had a better response when compared to a different treatment. Robert Andtbacka, M.D., from Huntsman Cancer Institute at the University of Utah and Howard L. Kaufman, M.D., from Rutgers Cancer Institute of New Jersey, led the multisite study, published May 26 online in the *Journal of Clinical Oncology*.

According to Andtbacka, "The goal of this targeted therapy is to treat late stage patients more effectively and with fewer side effects."

The researchers employed a genetically modified herpes virus, made by the pharmaceutical company Amgen, which was designed to replicate inside tumors and kill them. In addition, the virus contains a human gene to make granulocyte macrophage colony-stimulating factor (GM-CSF) with the goal of causing an anti-tumor immune response in the patient.

Frequently, tumor cells evade the immune system, but Andtbacka says the therapy was developed to retrain the immune system to recognize the melanoma as something that shouldn't be there. "Not only are the injected tumor cells destroyed, but the immune system is activated to fight the melanoma not only where we injected it, but also at distant sites."

In the clinical trial, patients with Stage IIIB, IIIC, or IV melanoma were randomized to receive either the virus therapy talimogene laherparepvec (T-VEC) injected directly into their tumors or to receive an injection of GM-CSF under the skin.

The researchers observed that T-VEC virus immunotherapy caused tumors to shrink compared to treatment with GM-CSF alone: 16 percent of T-VEC treated participants (n = 295) experienced a durable response,

meaning that their tumors shrank for >6 months, relative to 2 percent of the GM-CSF alone group (n = 141). While patients' lifespans, on average, were only extended by a small amount (4.4 months), 32 (11 percent) of the T-VEC recipients and one GM-CSF recipient (2 percent of T-VEC treated patients was cellulitis, a potentially dangerous skin infection (2.1 percent). "This safety profile is encouraging, since this is the first randomized trial of an oncolytic virus in patients with cancer," says Andtbacka.

T-VEC represents a novel treatment option for patients with injectable metastatic melanoma. This collaborative work was enabled by Amgen, manufacturer of the T-VEC virus and will be marketed under the name IMLYGICTM.

FDA approves first-of-its-kind product for the treatment of melanoma: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm469571.htm

Provided by University of Utah Health Sciences