FDA Approves Talimogene Laherparepvec (T-VEC) for Advanced Melanoma

Statement from Tim Turnham, Executive Director, Melanoma Research Foundation

Washington, D.C.—Today, the FDA approved Amgen’s drug Imlygic (Talimogene Laherparepvec, or T-VEC), for the treatment of unresectable Stage IIIIB, IIIC or IV metastatic melanoma. This approval brings a novel immunotherapy to people with advanced melanoma, many of whom have limited treatment options.

T-VEC represents a new approach to treating melanoma, a cancer that is increasing in incidence at an alarming rate. Unlike previously approved drugs that are given intravenously or by pill, this therapy is injected directly into the tumor and is the first intralesional therapy approved by the FDA for the treatment of cancer. T-VEC also represents an important milestone in using viruses as the vehicle to stimulate immune response and fight cancer.

Most importantly, however, this approval provides doctors and patients with another option for treating melanoma. Despite remarkable advances in the past four years, the majority of patients with metastatic melanoma still die from this cancer.

Phase III clinical trial results showed that among patients taking T-VEC, a genetically modified version of the herpes simplex virus, 64 percent responded to treatment, 47 percent of which saw a complete response. Significantly, more than 65 percent had response rates lasting at least one year and patients on T-VEC also experienced relatively mild side effects.

With seven new drugs approved for metastatic melanoma since 2011, we are optimistic that we are seeing the progress patients need to make this a chronic, manageable condition. The best way to ensure that the progress continues is to explore using these drugs, including T-VEC, in combinations.

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About Melanoma
Melanoma is one of the fastest growing cancers in the United States and can strike men and women of all ages, all races and skin types. With a one in 50 lifetime risk of developing melanoma, nearly 74,000 Americans are expected to be diagnosed with Stage I-IV melanoma and another 63,000 will be diagnosed with melanoma in situ – totaling nearly 137,000 total diagnoses. Melanoma is the most common form of cancer for young adults 25- to 29-years-old and the second most common cancer in adolescents and young adults 15- to 29-years-old.
The majority of melanomas occur on the skin; in fact, melanoma is the most serious type of skin cancer. Melanoma can also occur in the eye (ocular, or uveal melanoma), in mucous membranes (mucosal melanoma), or even beneath fingernails or toenails.

**About the Melanoma Research Foundation**
The Melanoma Research Foundation (MRF) is the largest independent organization devoted to melanoma. Committed to the support of medical research in finding effective treatments and eventually a cure for melanoma, the MRF also educates patients and physicians about prevention, diagnosis and the treatment of melanoma. The MRF is an active advocate for the melanoma community, helping to raise awareness of this disease and the need for a cure. The MRF’s website is the premier source for melanoma information seekers. More information is available at [www.melanoma.org](http://www.melanoma.org). Find the MRF on [Facebook](http://facebook.com) and [Twitter](http://twitter.com).