

MRA Lauds FDA Approval of First Vaccine for Melanoma Treatment

Washington, DC, October 28, 2015 – The Melanoma Research Alliance (MRA) welcomes another exciting new chapter in the treatment of melanoma with the news that the U.S. Food & Drug Administration (FDA) has given approval to Amgen's immunotherapy drug, IMLYGIC™, known as T-VEC for talimogene laherparepvec, for the local treatment of melanoma of the skin and lymph nodes that recurs after initial surgery.

T-VEC is the first oncolytic virus therapy, designed to destroy cancer cells, to be approved by the FDA. It is a virus that is injected directly into tumors where it both kills the tumor cells and concurrently releases an agent, GM-CSF, to stimulate the immune system.

The approval of T-VEC marks the 10th new therapy approved for melanoma in 5 years – "a truly unprecedented rate of progress," commented Robin Davisson, Ph.D., MRA's President and CEO-Elect. Founded eight years ago, MRA is the leading private global funder of research into the treatment and cure of melanoma, an often fatal skin cancer when metastasis occurs.

"The approval of T-VEC offers a unique weapon in the melanoma fighting arsenal that could well be exploited in other cancers, as has been the case with other melanoma treatments," added Louise M. Perkins, Ph.D., MRA's Chief Science Officer. "But while there has been astonishing progress with advances in targeted therapies and immunotherapies, much more is needed to be done to combat melanoma for all patients at every stage of disease."

Several studies are underway to assess T-VEC in combination with immune checkpoint inhibitors. MRA is investing in research to inform such combination therapies and expand the understanding of the combination of T-VEC and immune checkpoint blockade.

"The FDA's approval of another new immunotherapy drug is an important step forward in our fight against cancer, which still has a long way to go," said Debra Black, MRA Co-Founder and Chair of the Board. "We must continue to push the boundaries of scientific discovery to one day end death and suffering caused by melanoma."

Added Dr. Davisson: "Melanoma research has energized the entire field of oncology with advances in precision medicine approaches such as those used for BRAF-mutant melanoma and immunotherapies to treat advanced melanoma. Based on the powerful data and building on the lessons learned in melanoma, we are beginning to see melanoma treatments used effectively in different cancers, including lung cancer and others."

Since MRA launched in 2007, both <u>targeted</u> and <u>immune-based therapies</u> have been approved to treat melanoma, drastically changing the outlook for patients with melanoma and other cancers. MRA has funded research for all of these therapies and has invested more than \$26 million toward studying immunotherapy.

About The Melanoma Research Alliance (MRA)

MRA is a public charity formed in 2007 under the auspices of the Milken Institute, with the generous founding support of Debra and Leon Black. MRA is the largest private funder of melanoma research and has provided nearly \$68 million to research seeking to better prevent, diagnose, and treat melanoma, the deadliest type of skin cancer. Due to the ongoing support of its founders, 100% of every dollar MRA raises goes to support its melanoma research program. MRA's ability to fund wide-ranging research in melanoma is amplified by unique collaborations and partnerships with individuals, private foundations, and corporations. Visit www.CureMelanoma.org for more information, or follow us on Twitter or Facebook.

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