

Melanoma

Research Alliance

For Immediate Release

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Melanoma Research Alliance Welcomes FDA Approval of Pembrolizumab in Adjuvant Setting

WASHINGTON, D.C., February 20, 2019 – The Melanoma Research Alliance (MRA), the largest non-profit funder of melanoma research worldwide, applauds the U.S. Food & Drug Administration (FDA) approval of Merck’s pembrolizumab (Keytruda®) in the adjuvant setting for melanoma patients with lymph node involvement following complete lymph node resection.

Melanoma, the deadliest skin cancer, is the fifth most common cancer in the U.S. An estimated 9% of new cases have spread to lymph nodes or nearby sites around the tumor— referred to as [Stage III](#) disease—with correspondingly high risk of recurrence and death. Reducing the risk of recurrence after surgery represents a major opportunity to eliminate melanoma suffering and death.

“Over the last year we have seen a flurry of drug approvals that help reduce the risk of recurrence for high-risk Stage III melanoma following surgery while reducing treatment-related side effects,” said Chief Science Officer Marc Hurlbert, Ph.D. “This is important because it makes more treatment options available to patients and assists in making the decision to start adjuvant therapy that much easier for patients and their doctors.”

Pembrolizumab, an anti-PD-1 antibody, works by stimulating the patient’s immune system to attack melanoma by promoting the tumor-killing effectiveness of T cells. It was first approved for the treatment of unresectable or metastatic melanoma in 2014 and has since gained FDA approval to treat multiple cancers, including certain cancers of the lung, bladder and blood.

“Giving patients access to more, better tolerated, treatments to choose from at an earlier stage of disease is critical to achieving our mission of ending suffering and death due to melanoma,” said MRA President & CEO Michael Kaplan.

Without adjuvant therapy, about 60% of Stage III melanoma patients will relapse within three years of surgical resection. While adjuvant therapy works to reduce this risk, it does have its own range of side effects. Doctors and patients must work together to weigh the relative benefits of adjuvant therapy.

FDA approval of pembrolizumab in the adjuvant setting is based on results from the KEYNOTE-054 trial. In this phase-three study, pembrolizumab significantly reduced melanoma recurrence/death (26%) compared with patients receiving placebo (43%). The safety of pembrolizumab has been evaluated in

4,948 patients with various cancers and the most commonly reported adverse reactions were fatigue, rash, and nausea.

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About Melanoma Research Alliance (MRA)

Founded in 2007 under the auspices of the Milken Institute, with the generous support of Debra and Leon Black, the Melanoma Research Alliance exists to accelerate treatment options and find a cure for melanoma. As the largest nonprofit funder of melanoma research, it has dedicated over \$101 million and leveraged an additional \$101 million towards its mission. Through its support, MRA has championed revolutions in immunotherapy, targeted therapies, novel combinations and diagnostics. Due to the ongoing support of its founders, 100 percent of donations to MRA go directly to 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 <http://www.CureMelanoma.org> for more information.