

Melanoma

Research Alliance

For Immediate Release

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Melanoma Research Alliance Applauds Expanded Approval of Pembrolizumab to Patients with Stage 2 Disease

WASHINGTON, D.C., December 2, 2021 – The Melanoma Research Alliance (MRA), the largest non-profit funder of melanoma research worldwide, welcomes the U.S. Food and Drug Administration (FDA) decision to expand eligibility of Merck’s Keytruda (pembrolizumab) to include patients with Stage IIB and IIC melanoma.

Melanoma, the deadliest skin cancer, is the fifth most common cancer in the U.S. While surgery is curative for most patients with early-stage disease, an estimated 27% percent of patients with Stage II melanoma will experience a disease recurrence in the first five years following surgery.¹ Reducing the risk of recurrence after surgery represents a major opportunity to eliminate melanoma suffering and death.

“Over the last decade the treatment landscape for patients facing advanced melanoma has been dramatically changed by checkpoint immunotherapies,” says MRA Chief Science Officer Marc Hurlbert, PhD. “It’s great to see those same advancements now become available to patients with Stage II melanoma at risk for recurrence.”

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.

FDA approval of pembrolizumab in the adjuvant setting is based on results from the KEYNOTE-716 trial. In this randomized, Phase 3 study, patients with resected stage IIB or IIC melanoma who were treated with pembrolizumab demonstrated a 35% reduced risk of disease recurrence or death compared with patients receiving placebo.

“By giving patients a new option to prevent recurrence – at even earlier stages of disease – we are marking a new milestone in achieving MRA’s mission of ending suffering and death due to melanoma,” says MRA President & CEO Michael Kaplan.

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About Melanoma Research Alliance (MRA)

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 \$131 million and leveraged an additional \$415 million in collaborative and follow-on funding 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.

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