

We Welcome the Expanded Approval of Opdivo for Those With Stage 2 Melanoma

Reducing the risk of this deadly skin cancer recurring after surgery is an important goal, notes the Melanoma Research Alliance.

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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 Bristol Myers Squibb's Opdivo (nivolumab) to include patients with completely resected 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, up to one third of patients with stage IIB and up to half of patients with IIC melanoma will have a recurrence within five years. Reducing the risk of recurrence after surgery — and the progression to more advanced disease — is an important goal for clinicians and patients alike.

"Checkpoint inhibitor immunotherapies have transformed what it means to be diagnosed with and treated for advanced melanoma," says MRA chief science officer Joan Levy, PhD. "We are pleased to see these same transformational medicines are now becoming available to patients with Stage II melanoma who are at risk for recurrence."

Nivolumab, 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.

Nivolumab's expanded approval is based on results from the Phase 3 CheckMate-76K clinical trial, where patients with stage IIB or IIC melanoma who were treated with nivolumab following surgery, demonstrated reduced risk of recurrence or death by 58% vs placebo.

"The expanded approval of nivolumab gives patients with high-risk melanoma a new option to prevent recurrence following surgery," says MRA chief executive officer Marc Hurlbert, PhD. "This is an important milestone in MRA's mission of ending suffering and death due to melanoma."

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