

Melanoma

Research Alliance

MRA HAILS FDA APPROVAL OF FIRST COMBINATION IMMUNOTHERAPY FOR MELANOMA

Washington, DC, October 1, 2015 – The [Melanoma Research Alliance](#) (MRA) welcomes the U.S. Food and Drug Administration (FDA) decision to approve the use of Bristol-Myers Squibb’s (BMS) nivolumab (Opdivo®) and ipilimumab (Yervoy®) in combination as a treatment for patients with unresectable or metastatic melanoma without a BRAF mutation, known as BRAF wild-type melanoma. Approximately half of patients’ melanomas harbor BRAF mutations and the other half are BRAF wild-type.

The FDA’s accelerated approval of the two-drug regimen marks the first approval of combination immunotherapy treatments for advanced melanoma and comes less than one year after the first approval of nivolumab by the FDA.

[Ipilimumab](#) and [nivolumab](#) are two types of immunotherapy that help the body’s own immune system attack cancer cells. Ipilimumab is an anti-CTLA-4 inhibitor, while nivolumab is an anti-PD-1 drug; each was previously FDA-approved as monotherapy for the treatment of advanced melanoma.

The decision by FDA was based on the results of the CheckMate-069 trial, which looked at the combination of ipilimumab and nivolumab as compared to ipilimumab alone in previously untreated, BRAF wild-type patients. Recently reported [studies](#) showed the use of these two therapies in combination yielded better results than ipilimumab on its own in previously untreated melanoma patients – the so-called first-line setting.

“Based on the findings reported in scientific meetings and prestigious medical publications, the combination of ipilimumab and nivolumab are clearly active against melanoma. We’re pleased that both BMS and the FDA acted quickly so that patients will have access to the latest advances in melanoma treatment,” said **Louise M. Perkins**, Ph.D., MRA’s Chief Science Officer. “The pace of change in melanoma treatment is unprecedented and a testament to the amazing advances in both immunotherapy and targeted therapy research.”

Of the \$68 million the eight-year old MRA has thus far provided for melanoma research, more than \$26 million has gone to immunotherapy, such as immune checkpoint blockade approaches, including anti-PD-1 and anti-CTLA-4. Approved first for melanoma, nivolumab is also approved for squamous non-small cell lung cancer, and immune checkpoint drugs targeting CTLA-4 and PD-1 are being tested in more than 10 different types of cancer.

“The FDA’s latest approval signifies the rapidly changing treatment landscape for patients with melanoma,” said **Debra Black**, MRA Co-Founder and Chair of the Board. “We have more work to do to improve the survival rates for patients with advanced melanoma, particularly as rates of melanoma continue to rise, but this is an important decision that has the potential to benefit many patients.”

With this recent news, since MRA launched in 2007, nine therapies have been approved to treat melanoma including two approved drug combinations, drastically changing the outlook for patients with melanoma and other cancers.

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 percent 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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