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For Immediate Release

Cody R. Barnett, Director of Communications
M: (717) 880-7100
E-mail: cbarnett@curemelanoma.org

MRA Applauds FDA Approval of Nivolumab to Reduce the Risk of Melanoma Returning After Surgery

New Adjuvant Indication Offers Greater Effectiveness with Fewer Side Effects

WASHINGTON, DC, December 21, 2017 – The Melanoma Research Alliance (MRA) applauds the U.S. Food & Drug Administration (FDA) approval of Bristol-Myers Squibb's (BMS) nivolumab (Opdivo®) for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. This new indication for nivolumab offers patients a new, improved option to reduce the risk of melanoma returning with fewer side effects than currently available treatments.

Melanoma is the deadliest of the skin cancers and the fifth most common cancer overall in the U.S. An estimated 9% of new cases have spread to lymph nodes or nearby sites around the tumor— referred to as regional melanoma—with correspondingly high risk of disease recurrence and death in these patients. Reducing the risk that melanoma returns after surgery represents a major opportunity to eliminate melanoma suffering and death.

Nivolumab is an anti-PD-1 antibody that stimulates the body's own immune system to kill 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 approvals to treat multiple cancers including certain cancers of the lung, liver, kidney, bladder and blood.

Adjuvant therapy for melanoma aims to reduce the risk of cancer returning after surgery. Without adjuvant therapy, about 60% of Stage III melanoma patients will relapse within three years of surgical resection. While offering potential benefit, the two existing FDA-approved therapies carry significant risks and toxicities, including treatment-related death.

The FDA approval of nivolumab in the adjuvant setting is based on results from the CheckMate-238 trial. In this study, nivolumab significantly improved recurrence-free survival at 18 months (66%) versus standard ipilimumab (Yervoy®, 53%) in patients with resected Stage III or Stage IV melanoma. Further, it also had fewer serious treatment-related toxicities (Grade 3 or 4) (25% vs 55%, respectively) and fewer adverse events leading to treatment discontinuation (9% vs 42%, respectively).

"This is a clear win for patients," said MRA Chief Science Officer Louise M. Perkins, Ph.D. "Not only does nivolumab work better than existing treatments to reduce the risk of melanoma recurrence, it is also easier to tolerate, which means that more people will be able to take the drug."

MRA is the leading non-profit funder of research into the treatment and cure of melanoma, an often fatal skin cancer when metastasized. Since MRA launched in 2007, multiple targeted and immune-based therapies have been approved to treat melanoma, drastically changing the outlook for patients with melanoma and other cancers.

“The FDA’s expanded approval of nivolumab is a critical step in our ongoing fight against melanoma,” said MRA President & CEO Michael Kaplan. “We must continue to push research to expand our understanding about this disease and build on this understanding to benefit more and more cancers.”

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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 $88 million and leveraged an additional $89.5 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.