



TEN YEARS OF POWERFUL RESEARCH AND RESULTS

For Immediate Release

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MRA Hails FDA Approval of the First Targeted Oral Therapy to Reduce Risk of BRAF-Mutated Melanoma Returning After Surgery
New Adjuvant Indication Gives Patients Additional Options

WASHINGTON, DC, May 1, 2018 – The Melanoma Research Alliance (MRA) applauds the U.S. Food & Drug Administration (FDA) approval of Novartis’ dabrafenib (Tafinlar®) + trametinib (Mekinist)® for the adjuvant treatment of patients with BRAF-mutant melanoma. With today’s announcement, there are now four FDA approved treatments for melanoma adjuvant therapy encompassing immunotherapy and combination targeted therapy. This new [indication](#) gives patients access to the first orally administered melanoma adjuvant therapy with demonstrated improved recurrence-free survival.

Targeted therapy works by shutting down molecules inside tumor cells to slow their growth. [Dabrafenib](#) blocks the activity of a mutated version of a molecule called BRAF and [trametinib](#) blocks the activity of the MEK molecule that works in coordination with BRAF. Each drug was approved separately by the FDA to treat advanced BRAF-mutant metastatic melanoma in 2013 and the two were approved in combination in 2014.

[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.

“The approval of the first targeted therapy combination in the adjuvant setting is a marked advance for patients with BRAF-mutant melanoma,” said MRA Chief Science Officer Louise M. Perkins, Ph.D. “This orally administered regimen is a welcome addition that could ease the burden of treatment on patients.”

Melanoma is the deadliest form of skin cancer. Over 91,000 Americans are expected to be diagnosed with melanoma in 2018 and incidence of the disease continues to rise. While, the treatment outlook for melanoma has improved in recent years, further advances are needed to fully eliminate suffering and death related the disease.

The FDA approval for the use of dabrafenib + trametinib in the adjuvant setting is based on results from the COMBI-AD [study published in the New England Journal of Medicine](#). In the study, dabrafenib + trametinib was compared to placebo in patients with completely resected, stage III melanoma with BRAF V600E or V600K mutations. The combination vs. placebo improved recurrence-free survival at three years (58% vs 39%) and the three-year overall survival rate (86% vs 77%) was highly encouraging. Twenty-six percent of patients who received dabrafenib + trametinib discontinued treatment due to side effects.

MRA is the leading non-profit funder of research towards the treatment and cure of melanoma. 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.

“We now have more options than ever to reduce the risk of melanoma returning after surgery,” said MRA President & CEO Michael Kaplan. “This gives patients more choice to make the best decision for them to reduce risk while minimizing adverse reactions.”

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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 \$100 million and leveraged an additional \$90 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.