

Melanoma

Research Alliance

For Immediate Release

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Melanoma Research Alliance Hails FDA's First 'Triplet' Combination Approval for Melanoma

WASHINGTON, D.C., August 3, 2020 – The Melanoma Research Alliance (MRA), the largest non-profit funder of melanoma research worldwide, welcomes the decision by the U.S. Food and Drug Administration (FDA) approving Genentech's Tecentriq[®] (atezolizumab) plus Cotellic[®] (cobimetinib) and Zelboraf[®] (vemurafenib) for the treatment of BRAF V600 mutation-positive advanced melanoma patients.

The newly approved triplet treatment is the first FDA-approved combination for metastatic melanoma that brings together immunotherapy with targeted therapies. Tecentriq, an immunotherapy, works by releasing the brakes on the immune system allowing it to attack cancerous cells. Cotellic and Zelboraf are targeted therapies that shutdown specific pathways used by cancer to grow. Mutated copies of the BRAF V600 protein are found in about half of all melanomas.

"The approval of Tecentriq + Cotellic and Zelboraf marks the 13th new treatment approach approved for melanoma since 2011 and the first that combines checkpoint immunotherapy with BRAF/MEK inhibition," said Michael Kaplan, MRA President and CEO. "This is a huge step forward for patients with BRAF-mutant melanoma and provides even more options to treat their disease."

The FDA approval for Tecentriq + Cotellic and Zelboraf is based on results from the Phase 3 IMSpire 150 study. In the study, the triplet combination of Tecentriq + Cotellic and Zelboraf was compared to placebo + Cotellic and Zelboraf among patients with advanced BRAF-mutant melanoma. In data published June 13, 2020 by *The Lancet*, the triplet combination helped people live longer without their disease worsening (median PFS 15.1 months versus 10.6 months respectively). Rates of treatment related adverse events were similar between the two groups.

"This approval demonstrates the innovative spirit within the melanoma research community," says Dr. Marc Hurlbert, MRA Chief Science Officer. "It is the first of numerous combinations being studied that bring together checkpoint immunotherapy with targeted kinase therapies in the melanoma field's pursuit to improve patient outcomes."

Melanoma is the deadliest form of skin cancer and rates have increased over the last three decades. More than 100,000 people in the United States will be diagnosed with melanoma this year alone. Despite incredible

advances in melanoma research over the last decade that have supported the approval of 13 new treatment approaches, further advances are needed to fully eliminate suffering and death related to the disease.

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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 \$123 million and leveraged an additional \$307 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.

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