



For Immediate Release

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MRA APPLAUDS LATEST MELANOMA DRUG APPROVAL

New targeted therapy combination offers patients additional choice

WASHINGTON, D.C., June 27, 2018 – The Melanoma Research Alliance (MRA) today welcomed news that the U.S. Food & Drug Administration (FDA) has granted approval to Array BioPharma’s new targeted therapy combination of encorafenib plus binimetinib (BRAFTOVI and MEKTOVI), for the treatment of patients with unresectable or metastatic melanoma with a *BRAF*^{V600E} or *BRAF*^{V600K} mutation. This is the third combination targeted therapy aimed at shrinking melanoma tumors by interfering with mutated molecules that drive cancer.

Targeted therapy works by shutting down molecules inside tumor cells to slow their growth. Encorafenib blocks the activity of a mutated version of a molecule called BRAF and binimetinib blocks the activity of the MEK molecule that works in coordination with BRAF. The mutations targeted by this combination are present in about half of melanoma patients.

“The approval of encorafenib plus binimetinib marks the 12th new therapy approved for melanoma since 2011,” said Michael Kaplan, MRA President and CEO. “This is a truly remarkable rate of progress that will further benefit patients.”

The FDA approval for encorafenib plus binimetinib in melanoma is based on results from the Phase 3 COLUMBUS study. In the study, encorafenib plus binimetinib was compared to vemurafenib or single agent encorafenib in advanced BRAF-mutant melanoma. In data presented at the American Society of Clinical Oncology (ASCO) conference in June, the combination demonstrated overall survival (OS) of 33.6 months and progression-free survival (PFS) 14.9 months. In comparison, monotherapy with a BRAF inhibitor (vemurafenib) delivered an average OS of 16.9 months and a PFS of 7.3. The combination was well-tolerated by the majority of patients, with only 5% discontinuing treatment due to side effects.

This latest approval marks another milestone in the innovation melanoma is driving into oncology, notes Dr. Louise M. Perkins, MRA Chief Science Officer. “This kind of novel-novel combination, where neither drug was approved heretofore, has been elusive in oncology. This latest combination further solidifies the role for melanoma as a case study for modern drug development.”

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.

“This is an important step forward in the fight against melanoma, especially for patients with BRAF mutant disease” said Kaplan. “However, we must continue to push forward to one day end death and suffering caused by melanoma for all patients.”

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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 \$101 million and leveraged an additional \$101 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.