



May 29, 2013:

MRA Statement on FDA approval of two genetically-targeted melanoma therapies and companion diagnostic test

Today's announcement by the U.S. Food and Drug Administration (FDA) of approval for two new melanoma therapies that genetically target patients with advanced metastatic melanoma, the deadliest form of skin cancer, marks another milestone in the fight against this disease. GlaxoSmithKline's Tafinlar (dabrafenib) and Mekinist (trametinib) are designed for patients whose tumors express BRAF mutations, mutations present in approximately half of all melanoma tumors.

The companion THxID BRAF test was also approved as a means to determine which patients have the V600E or V600K BRAF mutations in their tumors, making them eligible for treatment with dabrafenib and trametinib. Companion diagnostics such as this new test help clinicians identify which treatments will benefit which patients.

As knowledge about the mechanisms of action that propel melanoma grows, researchers, clinicians and industry leaders are exploring multiple novel single agent and combinatorial approaches to combat this aggressive disease. The dramatic acceleration of the pace of discovery occurring today in melanoma is also fueling progress in other malignancies, making melanoma a "case study" for new approaches to therapy.

With today's approvals, the arsenal of weapons available to patients and their doctors expands from two to four, highlighting the extraordinary progress being made in the melanoma research field. With one person diagnosed with melanoma every eight minutes in the U.S., one person dying every hour, and incidence rising at an alarming rate, new melanoma treatments are urgently needed.

The Melanoma Research Alliance (MRA) is the largest private funder of melanoma research. MRA-funded investigators are researching several ways to treat melanoma, including targeted therapies such as those focusing on genetic mutations including BRAF, immunotherapies, and combination therapies. Research from more than 40 MRA-sponsored investigators will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago May 31-June 4.

About the Melanoma Research Alliance

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, having awarded \$48 million to the prevention, diagnosis and staging, and treatment of melanoma. MRA is poised to build on recent momentum in the field, accelerating the pace of scientific discovery and translation in order to eliminate suffering and death due to melanoma. MRA's ability to fund wide-

ranging research in melanoma is amplified by unique multi-faceted collaborations and partnerships with individuals, private foundations and corporations. For more information, please visit www.curemelanoma.org.

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