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Statement from Tim Turnham, Executive Director, Melanoma Research Foundation, Regarding Approval of Combination Therapy for Advanced Melanoma

For years, researchers have believed that the most effective approach to treating melanoma is likely to be in combining two or more drugs together. Today the FDA issued the first-ever approval of a drug combination for the treatment of this cancer. This combination involves a MEK inhibitor, trametinib, and a BRAF inhibitor, dabrafenib, both of which were approved by the FDA as single agents in May 2013.

Inhibition of BRAF, an area that is mutated in about half of all melanoma tumors, has been proven effective in the past, but efficacy of BRAF inhibitors only lasts a median of six months. Researchers have believed that combining a BRAF inhibitor with a MEK inhibitor could reduce toxicities associated with BRAF inhibition and could extend effectiveness of this therapeutic approach.

A Phase I/II study showed that the dabrafenib/trametinib combination had a higher response rate and longer duration of response than dabrafenib alone. This data was the basis of the FDA granting priority review for the combination. In Europe, approval for the combination was submitted in February 2013 and is being processed through normal channels.

The MRF has been watching for this approval with great interest, as resistance and partial responses to targeted monotherapy are major obstacles in cancer treatment. New treatment options, particularly combination therapies, are critical to improving the lives of people with melanoma, and this approval marks important progress.

Every hour of every day someone dies from melanoma. It is estimated that there will be over 77,000 melanoma diagnoses in 2013. FDA approval of this combination is a major step forward in the way melanoma is treated. The MRF encourages industry and regulators to build on this success by testing additional drug combinations, even when the drugs are not the property of a single company.

The MRF has been pushing for more combination therapies for years. In 2010, the organization formed the Melanoma Research Foundation Breakthrough Consortium (MRFBC) to accelerate and support combination research. Since then, the MRFBC has spearheaded combination therapy trials and created a Virtual Tissue Repository that will support faster accumulation of knowledge and narrowing in on the most promising targets.
The landscape for melanoma therapy has changed rapidly in recent years. The MRF continues its commitment to help bring promising new treatment options to the people who need them.

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**About Melanoma**

Melanoma is one of the fastest growing cancers in the United States and can strike men and women of all ages, all races and skin types. With a one in 50 lifetime risk of developing melanoma, nearly 77,000 Americans are expected to be diagnosed with the disease in 2013, resulting in over 9,400 deaths. Melanoma is the most common form of cancer for young adults 25- to 29-years-old and the second most common cancer in adolescents and young adults 15- to 29-years-old.

The majority of melanomas occur on the skin; in fact, melanoma is the most serious type of skin cancer. Melanoma can also occur in the eye (ocular, or uveal melanoma), in mucous membranes (mucosal melanoma), or even beneath fingernails or toenails.

**About the Melanoma Research Foundation**

The Melanoma Research Foundation (MRF) is the largest independent organization devoted to melanoma. Committed to the support of medical research in finding effective treatments and eventually a cure for melanoma, the MRF also educates patients and physicians about prevention, diagnosis and the treatment of melanoma. The MRF is an active advocate for the melanoma community, helping to raise awareness of this disease and the need for a cure. The MRF’s website is the premier source for melanoma information seekers. More information is available at [www.melanoma.org](http://www.melanoma.org). Find the MRF on [Facebook](http://www.facebook.com) and [Twitter](http://www.twitter.com).