Dabrafenib and trametinib approved for melanoma, 8/13:86

The FDA has approved GlaxoSmithKline's Tafinlar (dabrafenib) and Mekinist (trametinib) oral oncology treatments.

Tafinlar is indicated as a single-agent oral treatment for unresectable melanoma or metastatic melanoma in adult patients with BRAF V600E mutation. Tafinlar is not indicated for the treatment of patients with wild-type BRAF melanoma. Mekinist is indicated as a single-agent oral treatment for unresectable or metastatic melanoma in adult patients with BRAF V600E or V600K mutations. Mekinist is not indicated for the treatment of patients who have received a prior BRAF inhibitor therapy.

These mutations must be detected by an FDA-approved test, such as BioMérieux's THxID-BRAF companion diagnostic assay.

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