# ASCO: Dabrafenib/Trametinib active in metastatic melanoma

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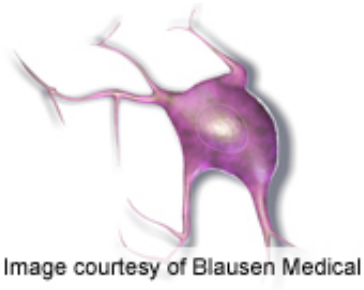

Image courtesy of Blausen Medical

(HealthDay) -- For patients with V600 *BRAF* -mutant solid tumors, treatment with the oral *BRAF* inhibitor dabrafenib and the oral *MEK 1/2* inhibitor trametinib is tolerated and has clinical activity in *BRAF* inhibitor-naive metastatic melanoma, according to a study released May 16 in advance of presentation at the annual meeting of the American Society of Clinical Oncology, held from June 1 to 5 in Chicago.

Jeffrey S. Weber, M.D., M.P.H., from the H. Lee Moffitt Cancer Center in Tampa, Fla., and colleagues enrolled 125 patients with V600 *BRAF*-mutant solid tumors, including 77 patients with metastatic melanoma who had not received prior treatment with *BRAF* inhibitors. Patients were treated at four escalating dose levels of 75/1, 150/1, 150/1.5, and 150/2 (mg twice daily/mg once daily) of dabrafenib/trametinib, and safety and efficacy were assessed.

The researchers found that the overall response rate was 56 percent among the 77 melanoma patients. At ascending dose levels, the confirmed response rate was 67, 64, 48, and 54 percent, respectively. The overall progression-free survival (PFS) was 7.4 months. For the corresponding dose levels, the median PFS was 8.7, 8.3, and 5.5 months, with PFS not mature for the 150/2 dose level. Among the cohort of 125 patients, there were two grade 5 adverse events, pneumonia and hyponatremia; the most common grade 3/4 adverse events were pyrexia, fatigue, and dehydration. Grade 2 or higher skin toxicity was seen in 14 percent of patients. Cutaneous squamous cell carcinoma and actinic keratoses each occurred in 2 percent of patients.

"It's fascinating to find such promising effects with this combination regimen. Not only are the two drugs causing shrinkage of the cancer, but we're seeing that a second anti-cancer therapy may actually suppress the side effects of the first," Weber said in a statement.

Several authors disclosed financial ties to pharmaceutical companies, including GlaxoSmithKline, which manufactures dabrafenib/trametinib.

**More information:** Abstract
More Information