Mekinist plus tafinlar approved for late-stage melanoma

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(HealthDay)—The U.S. Food and Drug Administration on Friday approved Mekinist for use with another drug, Tafinlar, to treat advanced melanoma that is spreading or cannot be removed by surgery.

Melanoma is the most deadly form of skin cancer, accounting for an estimated 9,480 American deaths last year, the FDA said Friday in a news release. Mekinist (trametinib) is newly approved to be used in combination with Tafinlar (dabrafenib). Both drugs were first sanctioned in May 2013 to be used by themselves to battle advanced melanoma, the agency said.

The combination therapy is newly approved for people who have certain mutations in the BRAF V600E and V600K genes, the FDA said. About half of melanoma cases have the mutated genes.

The combination therapy was clinically evaluated in 162 people. Of those treated, 78 percent had their cancer shrink or disappear for an average of 10.5 months, the agency said.

The most common side effects included fever, chills, rash, fatigue, nausea, diarrhea, abdominal pain and swelling of the arms and feet. More serious adverse reactions included bleeding, blood clots, heart failure, and skin and eye problems.

The drug combination can cause infertility and birth defects, the agency said, warning men and women of child-bearing age.

Both drugs are marketed by GlaxoSmithKline, based in Research Triangle Park, N.C.

More information: The FDA has more about this approval.