Medical Xpress

New drugs, diagnostic approved for advanced melanoma

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(HealthDay)—Two new drugs, Tafinlar (dabrafenib) and Mekinist (trametinib), have been approved by the U.S. Food and Drug Administration to treat advanced melanoma, the most dangerous form of skin cancer.

Melanoma, the leading cause of death from skin disease, is expected to be diagnosed in more than 76,000 people this year, and about 9,480 are expected to die from it, the FDA said Wednesday in a news release. Tafinlar is approved for people with an abnormality in the BRAF V600E gene, while Mekinist is approved for people with a mutation in either the BRAF V600E or V600K genes, the agency said.

A newly approved companion diagnostic, the THxID BRAF test, will help determine if a person has a mutation in either gene, the FDA said.

The most serious side effects reported in people getting Tafinlar included increased risk of a less severe form of skin cancer (cutaneous squamous cell carcinoma), fever, low blood pressure, shaking chills, dehydration, kidney failure and a rise in blood sugar, the agency said.

The most serious side effects of Mekinist included heart failure, lung inflammation, skin infection and loss of vision.

Both drugs also could cause infertility or harm a developing fetus, the FDA said.

Tafinlar and Mekinist are marketed by North Carolina-based GlaxoSmithKline. The THxID BRAF test is manufactured by bioMerieux, based in France.

More information: To learn more about these approvals, visit the FDA.

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