

New skin cancer drug approved by FDA

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Odomzo is a pill for locally advanced basal cell carcinoma.

(HealthDay)—A new drug to treat the most common form of skin cancer has been approved by the U.S. Food and Drug Administration.

Odomzo (sonidegib) was cleared to treat locally advanced basal cell carcinoma in patients who cannot undergo surgery or radiation therapy, or whose skin cancer has returned after surgery or [radiation therapy](#).

Skin cancer is the most common type of cancer, and basal cell carcinoma accounts for about 80 percent of non-melanoma skin cancers. Locally advanced basal cell [skin cancer](#) has not spread to other parts of the body, but cannot be cured with surgery or radiation.

Odomzo is a once-a-day pill designed to suppress a molecular pathway that is active in basal cell cancers, according to the FDA.

The drug's approval was based on a clinical trial that included 66 patients who took 200 milligrams (mg) of Odomzo a day and 128 patients who took 800 mg a day. Tumors shrank or disappeared in 58 percent of

patients in the 200-mg group. This benefit lasted from nearly two months to almost 19 months, and six months or longer in about half of the cases.

Response rates were similar among patients in the 800-mg group, but they had a higher rate of side effects, the FDA said.

At the lower dose, the most common side effects were muscle spasms, hair loss, taste problems, fatigue, nausea, musculoskeletal pain, diarrhea, decreased weight and decreased appetite. Some people also reported muscle pain, abdominal pain, headache, vomiting and itching.

Odomzo also poses a risk for serious musculoskeletal problems, including rare reports of muscle tissue breakdown.

The drug carries a Boxed Warning about the risk for fetal death or severe birth defects when taken by pregnant women. Doctors should check women for pregnancy before prescribing Odomzo, and both men and women should be warned about these risks and told to use birth control, the FDA said.

Odomzo is marketed by Novartis Pharmaceuticals of East Hanover, N.J. In 2012, Genentech's Erivedge (vismodegib) became the first FDA-approved drug to treat locally advanced and metastatic [basal cell carcinoma](#), meaning cancer that has spread to other parts of the body.

Basal cell skin cancers usually result from regular exposure to the sun and other forms of ultraviolet radiation, the FDA says.

More information: The U.S. National Cancer Institute has more about [skin cancer](#).

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