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New Treatment for Common Skin Cancer Has Some Problems

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Skin cancer treatment expert says medication approved by the FDA last week won't help that many people and has several serious side effects.



Diana Bolotin, M.D., Ph.D., is lukewarm about a new treatment for the most common form of skin cancer.

The assistant professor of dermatology at the University of Chicago Medicine (UCM) says while the medication known as Odomzo is a welcome advancement in the treatment of people with locally advanced basal cell carcinoma (BCC) it will help relatively few people since most patients with this condition can be treated with surgery.

“It's always good for the field to have multiple therapeutic options,” said Bolotin, who specializes in Mohs micrographic surgery (which is another treatment of BCC) and serves as the director of the specialty at UCM. “[But] to most people with a diagnosis of BCC, the new

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treatment doesn't mean very much.”

She said Odomzo will impact a small segment of the population that includes patients with Gorlin syndrome, a genetic condition that leads to formation of many BCCs and large inoperable BCC tumors.



“I've been at the University of Chicago since 2011 and have only come across a handful of patients who would qualify for such a treatment among the hundreds that we treat every year.” Bolotin said.

She noted that the response rate in the latest study for Odomzo was below 60 percent, “so it's certainly nowhere near as high as it would be if someone was a candidate for surgery.”

The cure rate is well above 90 percent with surgical treatments, even for operable recurrent BCCs, said Bolotin.

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Odomzo Uses the Hedgehog Pathway

Odomzo received approval from the Food and Drug Administration (FDA) last week for use in advanced stages of BCC.

According to the [FDA press release](#), “Odomzo is a pill taken once a day. It works by inhibiting a molecular pathway, called the Hedgehog pathway, which is active in basal cell cancers. By suppressing this pathway, Odomzo may stop or reduce the growth of cancerous lesions.”

“Our increasing understanding of molecular pathways involved in cancer has led to approvals of many oncology drugs in difficult-to-treat diseases for which few therapeutic options previously existed,” said Dr. Richard Pazdur, director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research in the press statement. “Thanks to a better understanding of the Hedgehog pathway, the FDA has now approved two drugs for the treatment of basal cell carcinoma just in the last three years.”

Erivedge was the first drug approved by the FDA in 2012 to treat locally advanced and metastatic basal cell carcinoma.

The effectiveness of Odomzo was established in a multi-center, double-blind clinical trial. In that study, 66 patients with locally advanced basal cell carcinoma were randomly assigned to receive 200 mg of Odomzo daily and 128 patients received 800 mg of Odomzo daily.

Researchers said 58 percent of patients treated with 200 mg had their tumors shrink or disappear. This effect lasted anywhere from two months to 18 months. About half of the tumor shrinkage lasted at least six months.

Response rates were similar in patients who received 800 mg of Odomzo daily.

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Serious Side Effects Noted

Odomzo carries a boxed warning, indicating it may cause death or severe birth defects in a developing fetus when administered to a pregnant woman.

The possibility of birth defects, in fact, is significant, said Bolotin.

“You'd have to think twice about using this in women of reproductive age and in men who could potentially father a child,” she said.

Bolotin added there are other side effects, including the loss of hair and taste.

“It's not a free ticket to get as much sun as you want.”

Diana Bolotin, M.D., Ph.D., University of Chicago Medicine

“This is a serious systemic therapy with potential side effects that patients and providers have to be aware of before it's started,” she said.

And, most certainly, use of the drug isn't a license to tan. “It's not a free ticket to get as much sun as you want,” she said.

Bolotin also cited several unknowns associated with the therapy, including how long someone should take the pill and the chance of recurrence after multiple years of use.

“Those [questions] still need to be worked out, and I'm sure there are studies looking at the long term effects and efficacy of this medication,” she said.

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A Common Type of Skin Cancer

Basal cell carcinoma accounts for about 80 percent of non-melanoma skin cancers.

Basal cell carcinoma starts in the top layer of the skin (epidermis) and usually develops in areas that have been regularly exposed to the sun and other forms of ultraviolet radiation.

According to the National Cancer Institute, the number of new cases of non-melanoma skin cancer appears to be increasing every year.

Locally advanced basal cell skin cancer refers to basal cancers that have not spread to other parts of the body and cannot be effectively treated with local treatments, specifically surgery and radiation.

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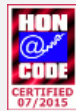
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