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US approves new drug against skin cancer

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A breakthrough drug that could extend survival in some patients with advanced skin cancer was approved on Wednesday by US regulators, offering the first new treatment for melanoma in 13 years.

Zelboraf was given the nod by the US Food and Drug Administration more than two months early, after a global clinical trial showed it could work better than chemotherapy by targeting a gene mutation found in about half of patients.

While the drug, made by Genentech, a US subsidiary of the Swiss pharmaceutical giant Roche, is far from a cure for people with metastatic melanoma, its approval was hailed as "a really big deal" by research advocates.

Zelboraf (vemurafenib) is the second melanoma drug to obtain approval this year, following Yervoy (ipilimumab) in March.

The treatment only works in patients with advanced melanoma whose tumors express a gene mutation called BRAF V600E, meaning it could help about 10,000 patients in the United States, according to experts.

Just a few treatments for melanoma currently exist, with little success in extending the life of patients. Most people diagnosed with advanced melanoma die within 11 months, said Tim Turnham of the Melanoma Research Foundation.

"This is a really big deal," Turnham told AFP. "This is two drugs after

13 years of nothing."

Zelboraf works by blocking a protein that is involved with cell growth.

"This is a whole new approach to tackling melanoma," explained Turnham. "This actually goes into the malignant tumor cells and shuts them down."

The FDA said the approval of Zelboraf comes with a diagnostic test called the cobas 4800 BRAF V600 mutation test to determine if patients have the type of cancer that the drug can treat.

"Today's approval of Zelboraf and the cobas test is a great example of how companion diagnostics can be developed and used to ensure patients are exposed to highly effective, more personalized therapies in a safe manner," said Alberto Gutierrez, director of the Office of In Vitro Diagnostic Device Evaluation and Safety in the FDA's Center for Devices and Radiological Health.

The regulatory agency had set a goal of deciding on the drug by late October, but issued the decision early after a promising results from an international trial of 675 patients with late-stage melanoma with the BRAF V600E mutation.

The FDA said that compared to another anti-cancer therapy, dacarbazine, Zelboraf showed longer overall survival, or the length of time between the start of treatment and the patient's death.

When measuring median survival, those on chemotherapy reached eight months with 64 percent of patients still living, while the median point for Zelboraf "has not been reached (77 percent still living)," the FDA said.

Early findings from that phase-three clinical trial were presented in

Chicago at June's conference of the American Society of Clinical Oncology (ASCO).

Lead author Paul Chapman, a physician at Memorial Sloan-Kettering Cancer Center in New York, called Zelboraf "the first successful melanoma treatment tailored to patients who carry a specific gene mutation in their tumor."

Side effects include joint pain, rash, hair loss, fatigue, nausea, and sensitivity to sun exposure, and those taking it should stay out of the sun, the FDA said.

Roche said the drug should be available in the United States in two weeks, and said it has submitted new drug applications for Zelboraf in the European Union, Australia, New Zealand, Brazil, India, Mexico and Canada.

However, Turnham noted that while the drug can work wonders for some patients, its effects do not typically last.

"For a lot of people, it works like magic. Two weeks after taking Zelboraf, the cancer is gone. It's amazing the way it melts tumors away.

"But the median response time is six months, then the tumors start coming back. There is a real need to find ways to extend that response time, perhaps by combining it with other drugs," he said.

The National Cancer Institute says 68,130 new cases of melanoma were diagnosed in the United States last year and about 8,700 people died from the disease.

According to the World Health Organization, skin cancer leads to 66,000 deaths annually worldwide, 80 percent of which involve melanomas.

More than half the patients are under age 59.

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