

FDA clears device for brain cancer first-of-a-kind

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WASHINGTON —

Device maker Novocure said Friday that the Food and Drug Administration approved its first-of-a-kind treatment that fights cancerous brain tumors using electrical energy fields.

The FDA approved the device for patients with aggressive brain tumors that have returned after treatment with chemotherapy and other interventions. Patients with recurring brain cancer usually live only a few months.

Studies showed that people using the device lived about as long as those taking chemotherapy, roughly six months. However, patients using the device had significantly fewer side effects.

For decades, doctors have treated cancer with three methods: drugs, radiation or surgery. Novocure's NovoTTF device represents a fourth approach.

The portable device uses electric fields to disrupt the division of cancer cells that allows tumors to grow and spread. The electric fields have little effect on healthy cells because they divide at a much slower rate, if at all, compared with cancer cells.

"The reason why this is so exciting is that we now have FDA approval of a totally new type of treatment for cancer," said Dr. Herb Engelhard, an associate professor of neurosurgery at the University of Illinois in Chicago. Engelhard helped conduct the study of NovoTTF but received no compensation from the company.

"All of us as investigators were skeptical at first, but I have seen the scans and I believe this is killing cancer cells in patients," Engelhard said.

The NovoTTF is a six-pound device that patients carry with them in a small bag. The electrical current is sent from the device to four electrodes which are attached to the patient's shaved head.

A panel of outside advisers to the FDA narrowly voted 7-6 in favor of the effectiveness of the device last month. The FDA is not required to follow such recommendations, though it often does.

A 237-patient study failed to show a survival benefit for patients using the device, compared with those taking chemotherapy. Patients in both groups lived just over six months, on average. However, those in the device group reported higher quality of life and did not have the side effects of chemotherapy, such as nausea, diarrhea and infection.

"This is as effective, or better, than anything that's ever been tried after standard treatment has failed. And while you're on it, you don't have any side effects from the treatment." said Al Musella, founder of the Musella Foundation for Brain Tumor Research and Information in Hewlett, N.Y. Musella's father and sister-in-law died of brain cancer.

The FDA approved the device specifically for a tumor type known as glioblastoma, the most aggressive form of brain cancer. Five-year survival for the disease is just 2 percent for patients over 45 years old, according to American Cancer Society. About 19,000 people in the U.S. are diagnosed with brain cancer each year, according to the National Cancer Institute.

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Standard treatment is six weeks of high-dose radiation along with a chemotherapy pill, and then additional chemotherapy for at least six months or until the tumor stops responding.

Novocure is a privately held company based in Portsmouth, N.H., and Haifa, Israel, where the NovoTTF device was invented. The company is testing its device in other types of cancer, including non-small cell lung cancer.

WFD Ventures, Pfizer Inc. and Johnson & Johnson are among the investors in the company.