

Medical. Healthcare**National Brain Tumor Society Statement on FDA Approval of Optune for Treatment of Glioblastoma Patients**

2015 OCT 19 (NewsRx) -- By a News Reporter-Staff News Editor at Pharma Business Week -- National Brain Tumor Society (NBTS) interim Chief Executive Officer David Arons issued the following statement on the U.S. Food and Drug Administration's (FDA) approval yesterday of Novocure's Optune, a medical device to treat newly diagnosed glioblastoma multiforme (GBM) patients in combination with the chemotherapy temozolomide (brand name: Temodar) following standard treatment of surgery and radiation therapy. Optune, previously called NovoTTF-100A, had originally received FDA approval to treat recurrent GBM patients in 2011:

"For patients diagnosed with glioblastoma, treatment options have been limited with no new advances in recent years. As such, NBTS is pleased by the FDA's decision to approve Optune based on necessary clinical safety and efficacy data. The approval of this device gives GBM patients another much needed option when considering a treatment regime that is right for them.

"NBTS is hopeful that the FDA's approval of this device influences others in the field to increase investment in this therapeutic area. Optune reveals a path to approval for this orphan indication and NBTS is encouraged that further research and development will produce treatments that continue to make strides in the extension of survival and enhancement of quality of life for all brain tumor patients.

"NBTS encourages GBM patients to ask their medical team about Optune and all potential therapeutic options in order to devise their best course of treatment. NBTS is also looking forward to continuing discussions with leaders in the field about the implications of this latest approval for brain tumor patients as well as brain tumor R&D by biopharmaceutical companies. Importantly, we also call upon health insurers to take action to provide adequate coverage of Optune in both the newly-diagnosed and recurrent settings. The cost of a new treatment should not be a barrier to care."

According to its announcement, the FDA based its approval of the expanded indication of the Optune device on results from a large phase 3 clinical trial conducted across a number of medical centers in the U.S., as well as Europe, South Korea, and Israel. The trial compared newly diagnosed GBM patients using Optune with temozolomide to those receiving temozolomide alone, following surgery and radiation. In the study, patients treated with the device and temozolomide lived a median of three months longer than those treated with the chemotherapy alone.

Optune is a portable battery or power-supply operated device, which produces changing electrical fields, called tumor treatment fields ("TTFs") intended to disrupt the growth of tumor cells. Patients wear a backpack containing the device's battery and electrodes directly on their scalp. Optune is meant to be used continuously.

Keywords for this news article include: Antineoplastics, Pharmaceuticals, Drugs, Medical, Surgery, Therapy, Oncology, Healthcare, FDA Actions, Glioblastoma, Temozolomide, Alkylating Agents, Government Agencies Offices and Entities.

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