Consumer Information on: NovoTTF-100A System - P100034

U.S. Food & Drug Administration

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: NovoTTF-100A System
PMA Applicant: NovoCure Ltd.
Address: 15022 MATAM Center, Haifa 31905, Israel
Approval Date: April 8, 2011
Approval Letter: http://www.accessdata.fda.gov/ cdrh_docs/pdf10/p100034a.pdf [1]

What is it? The NovoTTF-100A System treats recurrent glioblastoma multiforme (GBM). The NovoTTF-100A System is a portable battery or power-supply operated device which produces changing electrical fields, called tumor treatment fields ("TTFields") within the human body. TTFields are applied to the head of the patient by electrically-insulated surface electrodes.

How does it work? TTFields stop the growth of tumor cells resulting in cell death of the rapidly dividing cancer cells. The geometrical shape and scattering of the electrical charges within the dividing tumor cells allows TTF electrical fields to physically break up the tumor cell membrane. The frequency of the TTFields used for a particular treatment is specific to the size of the cell type being treated.

When is it used? The NovoTTF-100A System is intended as a treatment for adult patients (22 years of age or older) with confirmed glioblastoma multiforme, following confirmed recurrence in an upper region of the brain (supratentorial) after receiving chemotherapy. The device is intended to be used as a stand-alone treatment, and is intended as an alternative to standard medical therapy for recurrent GBM after surgical and radiation options have been exhausted.

What will it accomplish? In the clinical study, subjects with previously diagnosed

GBM who had a recurrence of their tumor or their condition worsened despite conventional therapy (surgery and chemo-radiotherapy followed by chemotherapy) were randomly assigned to receive either NovoTTF-100A stand-along treatment or the best standard of care effective chemotherapy (that is, the best effective chemotherapy treatment chosen for them by their physician).

The study showed that overall survival with the NovoTTF-100A System was comparable to that seen with active best standard of care chemotherapy. There was a slightly higher incidence of neurological adverse events in the NovoTTF-100A treated group (43.1% or 50 out of 116 subjects) compared to the best standard of care control group (36.3% or 33 out of 91 subjects). Mild to moderate skin irritation beneath the device electrodes was seen in 16% (18 out of 116 subjects) of NovoTTF-100A-treated subjects. NovoTTF-100A-treated subjects experienced a lower frequency of the classic adverse events as seen with chemotherapy (such as, gastrointestinal, hematological and infectious adverse events) with best standard of care. Quality of life surveys indicated an improved quality of life in the NovoTTF-100A recurrent GBM subjects compared to the best standard of care recurrent GBM subjects.

When should it not be used? The NovoTTF-100A System should **NOT** be used in patients with any of the conditions below that apply:

An active implanted medical device or a skull defect. Use of the device together with implanted electronic devices has not been tested and may theoretically lead to malfunctioning of the implanted device. Use of the device together with implanted medical devices or skull defects (that is, missing bone with no replacement), a shunt, or bullet fragments has not been tested and may possibly lead to tissue damage or cause the device stimulation ineffective.

- Examples of active electronic devices include: deep brain stimulators, spinal cord stimulators, vagus nerve stimulators, pacemakers, defibrillators, and programmable shunts

Any known sensitivities to conductive hydrogels like the gel used on electrocardiogram (ECG) stickers or TENS (transcutaneous electrical nerve stimulation) electrodes. In this case, skin contact with the electrode gel used with this device may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Additional information: Summary of Safety and Effectiveness and labeling [2] are available online.

Other Resources:

NIH - MedlinePlus-Brain Tumor-Primary-Adults [3]

SOURCE [4]

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http://www.mdtmag.com/news/2011/05/consumer-information-novottf-100a-system-p100034

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