Protocol Title: Pivotal, Randomized, Open-label Study of Tumor Treating Fields (TTFields, 150kHz) Concomitant with Gemcitabine and Nab-paclitaxel for Front-line Treatment of Locally-advanced Pancreatic Adenocarcinoma (PANOVA-3)

Target Population: Pancreatic Adenocarcinoma

Summary: The study is a prospective, randomized controlled phase III trial aimed to test the efficacy and safety of Tumor Treating Fields (TTFields) in combination with gemcitabine and nab-paclitaxel, for front line treatment of locally-advanced pancreatic adenocarcinoma. The device is an experimental, portable, battery operated device for chronic administration of alternating electric fields (termed TTFields or TTF) to the region of the malignant tumor, by means of surface, insulated electrode arrays.

Key Inclusion Criteria:
- ≥ 18 years of age.
- Life expectancy of ≥ 3 Months.
- Histological / cytological diagnosis of de novo Adenocarcinoma of the Pancreas.
- Unresectable, locally advanced stage disease according to the following criteria:
  - Head / Uncinate Process:
    - Solid tumor contact with SMA > 180° and CA > 180°, and contact with 1st Jejunal SMA Branch
    - Contact with most proximal draining Jejunal Branch into SMV
  - Body and Tail:
    - Solid tumor contact of > 180° with SMA or CA, and contact with CA & Aortic Involvement
    - Unreconstructible SMV/PV due to tumor involvement or occlusion (can be due to tumor or bland thrombus)
    - No distant metastasis, including non-regional lymph node metastasis
    - No borderline resectable
- ECOG Performance Score 0-2.
- Amenable and assigned by the investigator to receive therapy with Gemcitabine and nab-Paclitaxel.
- Able to operate the NovoTTF-100L(P) System independently or with the help of a caregiver.

Key Exclusion Criteria:
- Prior palliative treatment (e.g. surgery, radiation) to the tumor.
- Cancer requiring anti-tumor treatment within the 5 Years before inclusion, excluding treated stage I prostate cancer, in situ cervical or uterus cancer, in situ breast cancer and non-melanomatous skin cancer.
- Serious co-morbidities.
- Concurrent anti-tumor therapy beyond Gemcitabine and nab-Paclitaxel.
- Implantable electronic medical devices in the torso, such as pacemakers.
- Known severe hypersensitivities to medical adhesives or hydrogel, or to chemotherapies used in this trial.
- Pregnancy or breast-feeding.
- Unable to follow the protocol for medical, psychological, familial, geographic or other reasons.
- Admitted to an institution by administrative or court order.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03377491