



**JOHN WAYNE
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Sponsor

Nativis, Inc.

**Saint John's
Health Center**

 **PROVIDENCE** Health & Services

CLINICAL TRIAL ANNOUNCEMENT

A Feasibility Study of the Nativis Voyager System in Patients With Recurrent Glioblastoma Multiforme (GBM)

This feasibility study will assess the effects of the Nativis Voyager therapy in patients with recurrent GBM who have either failed standard of care or are intolerant to therapy.

Nativis Voyager™ System:

A non-invasive, non-thermal, battery-operated, mobile investigational medical device that is placed on the patient's head above the target treatment site (solid tumor). The device provides anti-cancer treatment through the emission of continuous, low level radio frequency energy (RFE). A treatment cycle is defined as 28 days of investigational treatment (Voyager therapy) administered to the head (non-invasively) continuously for 24 hours per day 7 days per week.

Patients with recurrent GBM and have either failed prior standard-of-care therapy, including radiation therapy and/or chemotherapy, or are intolerant of therapy will be considered for inclusion in the study. Patients who have additionally received other investigational therapies that are no longer effective for the given patient or are intolerant to the investigational therapy may be considered for inclusion in this study.

Patients will be treated with Voyager therapy in combination with standard chemotherapy lomustine (CCNU). Lomustine (110 mg/m² p.o.) is administered once in every six weeks (42 days) in accordance with standard NCCN guidance for recurrent GBM.

Key Inclusion Criteria:

- Histologically confirmed diagnosis of GBM.
- Failed or intolerant to radiotherapy and temozolomide therapy
- Progressive disease with at least one measureable lesion on MRI or CT.
- At least 18 years of age.
- KPS ≥ 60.
- Adequate organ and marrow function.

Key exclusion

- Patient has received bevacizumab (Avastin).
- Any condition, including compromised pulmonary function, that would preclude the use of lomustine.
- Patients with a baseline below 70% of the predicted Forced Vital Capacity (FVC) or Carbon Monoxide Diffusing Capacity (DLCO)