



**JOHN WAYNE  
CANCER INSTITUTE**  
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**Sponsor**

Nativis, Inc.

**Saint John's  
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# CLINICAL TRIAL ANNOUNCEMENT

## Nativis Voyager for Newly Diagnosed GBM (NAT109)

This feasibility study will assess the effects of the Nativis Voyager therapy in patients newly diagnosed with GBM. The study will enroll and treat up to 11 subjects and will be combined with standard of care radiotherapy and temozolomide.

### Nativis Voyager® A1A 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, ultralow level radio frequency energy (uIRFE®).

### Study Period:

Subjects will continue study treatment until disease progression, unacceptable clinical findings attributed to the investigational device, or patient withdraws from the study.

### Study Arm:

**Experimental:** Nativis Voyager A1A (investigational therapy) in combination with standard of care therapy following resection.

**Standard of care therapy** includes radiotherapy plus concomitant temozolomide followed by maintenance temozolomide.

### Key Inclusion Criteria:

- Pathological evidence of GBM using World Health Organization (WHO) classification.
- Maximal debulking surgery.
- Patients may enroll if they received Gliadel wafers before entering the trial.
- Additional treatments received prior to enrollment will be considered an exclusion.
- At least 18 years of age.
- Karnofsky Performance Scale (KPS)  $\geq$  60.
- Life expectancy > 3 months.
- Able to start investigational treatment within 28 days (i.e.,  $\leq$  28 days) from tumor resection surgery, and standard of care radiotherapy and temozolomide between 2 and 6 weeks from tumor resection surgery.

Please feel free to contact the clinical trial team to learn more about this study.