



**JOHN WAYNE  
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#### Sponsor

Medicenna Therapeutics, Inc

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# CLINICAL TRIAL ANNOUNCEMENT

## Convection-Enhanced Delivery (CED) of MDNA55 in Adults With Recurrent or Progressive Glioblastoma

Official Title: An Open-Label Non-Randomized, Multi-Center Phase-2 Study of Convection-Enhanced Delivery (CED) of MDNA55 in Adults With Recurrent or Progressive Glioblastoma

This is a single-arm, open-label, multicenter study in approximately 43 adults with primary (de novo) Glioblastoma that has recurred or progressed after failure of first-line therapy [according to Response Assessment in Neuro-Oncology (RANO) criteria]. Eligible subjects will receive intratumoral infusion of MDNA55 administered via convection-enhanced delivery (CED).

MDNA55, is a fusion protein comprising a genetically engineered Interleukin-4 (IL-4) linked to a modified version of the *Pseudomonas aeruginosa* exotoxin A (PE).

#### Key Inclusion Criteria:

- $\geq 18$  years old, have access to archival tissue from first diagnosis of Glioblastoma and have a life expectancy  $\geq 12$  weeks
- Histologically proven, primary (de novo) GB that has recurred or progressed (first or second recurrence, including this recurrence) after treatment(s) including surgery and radiotherapy with or without chemotherapy (according to local practice; Stupp protocol, Stupp et al., 2005) and following discontinuation of any previous standard or investigational lines of therapy
- Subjects must have evidence of tumor recurrence/progression as determined by standard RANO criteria:
  - Includes primary Glioblastoma
  - Screening MRI must be performed within 14 days prior to enrollment, and subjects receiving steroids must be on a stable, or decreasing dose for at least 5 days prior to imaging
  - More than 12 weeks must have elapsed since the completion of radiation therapy at the time of study entry
- Recurrent tumor must be a solid, supratentorial, contrast-enhancing Glioblastoma no smaller than 1 cm and no larger than 4 cm in diameter as assessed by the Imaging Core Laboratory based on MRI taken within 14 days prior to catheter placement
- Subjects will be ineligible for participation if they meet any of the following criteria:
  - Temozolomide (standard induction and / or maintenance dosing) within the past 4 weeks prior to planned infusion
  - "Metronomic" Temozolomide (low-dose, continuous administration) within the past 7 days prior to planned infusion
  - Nitrosoureas within the past 6 weeks prior to planned infusion
  - Treatment with any other cytotoxic or investigational agent within the past 4 weeks prior to planned infusion