JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

# CLINICAL TRIAL ANNOUNCEMENT

## Convection-Enhanced Delivery (CED) of MDNA55 in Adults With Glioblastoma at First Recurrence or Progression

**For more information, please contact the Neuro-Oncology Clinical Trial Team at:**
neuro.oncology@jwci.org
310-829-8265

**Clinical Trial Investigators**

Achal S. Achrol, MD

Garni Barkhoudarian, MD

Daniel Kelly, MD

Santosh Kesari, MD, PhD, FANA, FAAN

Steven O'Day, MD

**Clinical Trial Team**

Najee Boucher, CRA
najee.boucher@providence.org
310-582-7460

Jaya Gill, RN, BSN
jaya.gill@providence.org
310-582-7437

Annie Heng, RN, BSN
HengA@jwci.org
310-582-7457

Marlon Garzo Saria, PhD, RN, AOCNS, FAAN
SariaM@jwci.org

**Sponsor**

Medicenna Therapeutics, Inc.

Saint John's Health Center
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Official Title: An Open-Label Non-Randomized, Multi-Center Phase-2 Study of Convection-Enhanced Delivery (CED) of MDNA55 in Adults With Glioblastoma at First Recurrence or Progression

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:

- ≥ 18 years old, have access to archival tissue from first diagnosis of Glioblastoma and have a life expectancy ≥ 12 weeks
- Histologically proven, primary (de novo) Glioblastoma that has recurred or progressed after only 1 standard treatment regimen including surgery and radiotherapy with or without chemotherapy (according to local practice; Stupp protocol, Stupp et al., 2005)
- Subjects must have evidence of first 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
- If temozolomide was received as part of first line therapy, subjects must have recovered from the toxic effects of temozolomide and be at least 23 days from last dose prior to start of CED infusion
- Karnofsky Performance Score (KPS) ≥ 70