



**JOHN WAYNE
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CLINICAL TRIAL ANNOUNCEMENT

A Study of DSP-7888 Dosing Emulsion in Combination With Bevacizumab in Patients With Recurrent or Progressive Glioblastoma Following Initial Therapy

This is a randomized, active-controlled, multicenter, open-label, parallel groups, Phase 2 study of **DSP-7888** Dosing Emulsion plus Bevacizumab versus Bevacizumab alone in patients with recurrent or progressive glioblastoma multiforme (GBM) following treatment with first line therapy consisting of surgery and radiation with or without chemotherapy.

DSP-7888 Dosing Emulsion is a synthetic peptide vaccine that consists of 2 synthetic peptide constructs: DSP-7888-K (major histocompatibility complex [MHC] Class I peptide) and DSP-7888-H (MHC Class II peptide).

Glioblastoma, with its exceedingly poor prognosis, remains a disease with a significant unmet medical need; and there remains an ongoing need for new therapies in this disease. A high percentage of GBM tumors express WT1, and WT1 may be critical to the maintenance of the oncologic state in GBM; therefore, it is a potentially important target for the development of anti-GBM therapies. WT1 vaccines have demonstrated preliminary evidence of activity in patients with GBM, and DSP-7888 Dosing Emulsion has demonstrated safety in the doses proposed for this study. The addition of Bev may further enhance the activity of a tumor vaccine.

Key Inclusion Criteria:

- Histologically confirmed diagnosis of supratentorial GBM (Grade 4 astrocytoma).
- Radiographic evidence of first recurrence or progression of GBM following primary therapy consisting of surgery (biopsy or resection) and chemoradiation; patients may have undergone a second debulking surgery following initial recurrence or progression. Patients whose tumors are O6 methyl guanyl-methyltransferase (MGMT) methylated-promoter negative need not have received chemotherapy in the past to be eligible.
- Human leukocyte antigen type HLA-A*02:01, HLA-A*02:06, or HLA-A*24:02.
- Age ≥ 18 .
- KPS score of ≥ 60 .

Key Exclusion Criteria:

- Prior therapy with Bevacizumab (Avastin)