Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude de phase II, randomisée, multicentrique, visant à comparer le DSP-7888, administré sous forme d'émulsion, en association avec le bévacizumab comparé au bévacizumab en monothérapie chez les patients présentant un glioblastome récurrent ou progressif après le premier traitement
Protocole ID	DSP7888-201G
ClinicalTrials.gov ID	NCT03149003
Type(s) de cancer	Cerveau (SNC)
Phase	Phase II
Stade	Récidive
Type étude	Traitement
Médicament	DSP-7888 Dosing Emulsion + Bevacizumab vx Bevacizumab seul
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	Sherbrooke
Investigateur principal	Dr David Fortin
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Statut	Fermé
But étude	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.
Critères d'éligibilité	• Patients or their legal representatives must be able to provide written informed consent. • 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-methyl-transferase (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. • Serum creatinine value <2X the upper limit of normal (ULN) for the reference laboratory. • Alanine aminotransferase/aspartate aminotransferase <3X the ULN and total bilirubin <2× the ULN for the reference laboratory. • Patients must have recovered from the effect of all prior therapy to Grade 2 or less. • Patients must be at least 28 days from any major surgery, and any surgery incisions or wounds must be completely healed. • Patients must be at least 12 weeks from the completion of prior radiation therapy (RT) in order to discriminate pseudo progression of disease from progression. • Patients must be at least 4 weeks from the completion of prior systemic or intracranial chemotherapy. • For patients who are not receiving therapeutic anticoagulation treatment, an international normalized ratio (INR) and a PTT ≤ 1.5 × the ULN; patients who are receiving anticoagulation treatment should be on a stable dose.

Critères d'exclusion	• Prior therapy with Bev. • Any anti-neoplastic therapy, including RT, for first relapse or recurrence. • Evidence of leptomeningeal spread of tumor or any history, presence, or suspicion of metastatic disease extracranially. • Evidence of impending herniation on imaging. • Patients with infections that have required treatment with systemic antibiotics within 7 days of first dose of protocol therapy. • The need for systemic glucocorticoids in doses in excess of 4 mg/day of dexamethasone or in comparable doses with other glucocorticoids. • Treatment with any investigational agents within 5 half-lives of the agent in question or, if the half life is unknown, within 28 days of enrollment. • Pregnant or lactating females. • Prior history of malignancy within 3 years of enrollment other than basal or squamous cell carcinoma of the skin, cervical intra-epithelial neoplasia, in situ carcinoma of the breast, or prostate cancer treated with surgery or RT with a prostate specific antigen of <0.01 ng/mL. • Patients with active autoimmune diseases within 2 years of enrollment into the study including, but not limited to, rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, Sjogren's syndrome, Wegener's granulomatosis, ulcerative colitis, Crohn's disease, myasthenia gravis, Graves' disease, or uveitis except for psoriasis not requiring systemic therapy, vitiligo or alopecia areata, or hypothyroidism; if an autoimmune condition has been clinically silent for 12 months or greater, the patient may be eligible for enrollment. • Patients on immunosuppressive therapies; the use of topical, inhalational, ophthalmologic or intra articular glucocorticoids, or the use of physiologic replacement doses of glucocorticoids are permitted. • Patients with primary immunodeficiency diseases. • Patients with significant bleeding in the preceding 6 months or with known coagulopathies. • History of abdominal fistula, intestinal perforation, or intra-abdominal abscess in the preceding 12 months. • Known history of human immunodeficiency virus (HIV) infection, active hepatitis B, or untreated hepatitis C; patients who have completed a course of anti-viral treatment for hepatitis C are eligible. • Significant cardiovascular disease, including New York Hospital Association Class III or IV congestive heart failure, myocardial infarction within 6 months of enrollment, unstable angina, poorly controlled cardiac arrhythmias, or stroke within the preceding 6 months. • Any other uncontrolled inter current medical condition, including systemic fungal, bacterial, or viral infection; uncontrolled hypertension; diabetes mellitus; or chronic obstructive pulmonary disease requiring 2 or more hospitalizations in the preceding 12 months. • Known sensitivity to Bev or any of the components of DSP-7888 Dosing Emulsion.