MT2019-35: NeurotoxicityProphylaxis with Intrathecal Dexamethasone and Simvastatin in Adults Receiving AxicabtageneCiloleucel (Axi-Cel) Treatment

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years to 80 Years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

• 18- 80 years of age
• One of the following histologies:
• Diffuse large B-cell lymphoma (DLBCL) not otherwise specified, or
• Primary mediastinal B-cell lymphoma, or
• High grade B-cell lymphoma, or
• DLBCL arising from follicular lymphoma
• Disease status:
• Chemotherapy refractory disease after â‰¥2 lines of chemotherapy, or
• Relapsed with no remission after â‰¥1 lines of salvage chemotherapy, or
• Relapsed following autologous hematopoeitic stem cell transplantation (and failed at least 2 prior lines of therapy including high dose chemotherapy). If salvage therapy is given post auto HCT, the subject must have no complete response, or relapse after the last line of therapy
• Performance Status
• ECOG performance status 0-2
• Adequate organ function defined as:
• Renal function defined as:
• eGFR â‰¥ 30 mL/min/1.73 m^2
• Liver function defined as:
• ALT and AST â‰¤ 5 times the ULN for age (unless due to disease)
• Bilirubin â‰¤ 2.0 mg/dl with the exception of patients with Gilbert syndrome; may be included if their total bilirubin is â‰¤ 3.0 x ULN and direct bilirubin â‰¤ 1.5 x ULN
• Hemodynamically stable and LVEF â‰¥ 40% confirmed by echocardiogram or MUGA
• Women of childbearing potential and men with partners of child-bearing potential must agree to use of contraception for the duration of treatment as outlined in axi-cel protocol.
• Able to provide written voluntary consent (or LAR consent for adults with diminished capacity) prior to the performance of any research related tests or procedures
• Availability of a certified practitioner to perform the lumbar punctures

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Exclusion Criteria:

• Allergies, or intolerance to simvastatin or dexamethasone
• Already receiving a statin drug for hypercholesterolemia and unwilling to change medication to 40 mg/day of simvastatin
• Active uncontrolled CNS lymphoma. Patients with history of CNS lymphoma who have been adequately treated are eligible
• Presence of Grade 2 to 4 acute or extensive chronic graft-versus-host disease (GVHD).
• Uncontrolled active hepatitis B or hepatitis C
• Active HIV infection
• Uncontrolled acute life threatening bacterial, viral or fungal infection
• Unstable angina and/or myocardial infarction
• Risk factors that preclude a safe lumbar puncture (high intracranial pressure, bleeding diathesis that cannot be reversed or corrected, need for uninterrupted anticoagulation, platelets < 50K that cannot be corrected with transfusional support
• Pregnant or breastfeeding as agents used in this study are Pregnancy Category C (dexamethasone) and X (simvastatin). Females of childbearing potential must have a negative pregnancy test (serum or urine) within 7 days of study registration.

Conditions & Interventions

Interventions:
Drug: Simvastatin, Drug: Dexamethasone
Conditions:
Lymphoma
Keywords:
Lymphoma, CAR-T, Neurotoxicity, CRS, Dexamethasone, Simvastatin, Clinics and Surgery Center (CSC)

More Information

Description: This study is designed to determine the feasibility of administration, safety and tolerability of IT dexamethasone and simvastatin therapy in patients receiving axi-cel therapy while providing preliminary estimates of efficacy.
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