Essai Clinique

Généré le 16 mai 2024 à partir de

Titre	A Phase 3, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination With Rituximab and Lenalidomide (R2) Compared to R2 in Subjects With Relapsed or Refractory Follicular Lymphoma
Protocole ID	EPCORE FL-1
ClinicalTrials.gov ID	NCT05409066
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase III
Stade	Lymphome folliculaire/zone marginale
Type étude	Clinique
Médicament	Epcoritamab en association avec rituximab et lénalidomide (R2) comparé à R2
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Statut	Actif en recrutement
Date d'activation	26-10-2023
But étude	Follicular Lymphoma (FL) is the second most common B-cell cancer and the most common type of cancer of lymphocytes. Unfortunately, this disease is incurable with conventional treatment and the disease recurs in almost all patients. This study will assess how safe and effective epcoritamab is in combination with lenalidomide and rituximab (R2) in treating adult participants with relapsed or refractory (R/R) FL. Adverse events and change in disease condition will be assessed. Epcoritamab is an investigational drug being developed for the treatment of FL. Study doctors put the participants in 1 of 3 groups, called treatment arms. Each group receives a different treatment. Enrollment to one of the groups is closed. Around 520 adult participants with R/R FL will be enrolled in approximately 300 sites across the world. Participants will receive R2 (375 mg/m^2 intravenous infusion of rituximab up to 5 cycles and oral capsules of 20 mg lenalidomide for up to 12 cycles) alone or in combination with subcutaneous injections of epcoritamab for up to 12 cycles (each cycle is 28 days).There may be higher treatment burden for participants in this trial compared to their standard of care. Participants will attend regular visits during the study at a hospital or clinic. The effect of the treatment will be checked by medical assessments, blood tests, checking for side effects and completing questionnaires.

Critères d'éligibilité	• Eastern Cooperative Oncology Group (ECOG) performance status score 0 to 2.
	• Participant has:
	  • Fluorodeoxyglucose-positron emission tomography (FDG-PET) scan demonstrating positive lesion compatible with computed tomography (CT) or magnetic resonance image (MRI)-defined anatomical tumor sites AND
	  • >= 1 measurable nodal lesion (long axis > 1.5 cm) or >= 1 measurable extra-nodal lesion (long axis > 1.0 cm) on CT scan or MRI.
	• Histologically confirmed classic follicular lymphoma (FL) [previously Grade 1 to 3a FL] stage II, III, or IV with no evidence of histologic transformation to an aggressive lymphoma and CD20+ on a representative tumor biopsy based on the pathology report.

	• Relapsed or refractory (R/R) disease to at least one prior systemic regimen that contained an anti-CD20 monoclonal antibody (mAb) in combination with chemotherapy. (Participant who received only prior anti-CD20 mAb monotherapy and/or radiation therapy is not eligible.) • Eligible to receive R2 per investigator determination
Critères d'exclusion	• Documented refractoriness to lenalidomide. • Have lenalidomide exposure within 12 months prior to randomization.