Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	Une étude multicentrique randomisée de phase 2/3 de MOR00208 avec bendamustine versus rituximab avec bendamustine chez des patients atteints d'un lymphome diffus à grandes cellules B récidivant ou réfractaire (LDGCB RR) qui ne sont pas admissibles à la chimiothérapie à haute dose (CHD) et à la greffe autologue de cellules souches (GACS)
Protocole ID	B-MIND
ClinicalTrials.gov ID	NCT02763319
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase II
Stade	Lymphome diffus à grandes cellules B
Type étude	Traitement
Médicament	MOR208 + Bendamustine vs Rituximab + Bendamustine
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
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Statut	Fermé
But étude	The purpose of the study is to compare the safety and efficacy of MOR208 with BEN versus RTX with BEN in adult patients with relapsed of refractory DLBCL.
Critères d'éligibilité	• Age ≥18 years • Histologically confirmed diagnosis, according to the World Health Organization (WHO, 2008) classification, of: DLBCL NOS, THRLBCL, EBV-positive DLBCL, composite lymphoma with a DLBCL component with a DLBCL relapse subsequent to DLBCL treatment, disease transformed from an earlier diagnosis of low grade lymphoma (i.e. an indolent pathology such as follicular lymphoma, marginal zone lymphoma) into DLBCL with a DLBCL relapse subsequent to DLBCL treatment. • Fresh tumour tissue for central pathology review must be provided as an adjunct to participation in this study. Should it not be possible to obtain a fresh tumour tissue sample, archival paraffin embedded tumour tissue acquired ≤3 years prior to screening for this protocol must be available for this purpose. • Patients must have: • relapsed or refractory DLBCL • at least one bidimensionally measurable disease site. The lesion must have a greatest transverse diameter of ≥1.5 cm and greatest perpendicular diameter of ≥1.0 cm at baseline. The lesion must be positive on PET scan • received at least one, but no more than three previous systemic therapy lines for the treatment of DLBCL. At least one previous therapy line must have included a CD20-targeted. • ECOG 0 to 2 • Patients after failure of ASCT or patients considered in the opinion of the investigator currently not eligible for HDC with subsequent ASCT. • Patients must meet the following laboratory criteria at Screening: • ANC ≥1.5 × 109/L (unless secondary to bone marrow involvement by DLBCL) • PLTs ≥90 × 109/L (unless secondary to bone marrow involvement by DLBCL) and absence of

	active bleeding • total serum bilirubin ≤2.5 × ULN unless secondary to Gilbert's syndrome (or pattern consistent with Gilbert's) or documented liver involvement by lymphoma. Patients with Gilbert's syndrome or documented liver involvement by lymphoma may be included if their total bilirubin is ≤5 x ULN • ALT, AST and AP ≤3 × ULN or <5 × ULN in cases of documented liver involvement by lymphoma • serum creatinine ≤2.0 x ULN or creatinine clearance must be ≥40 mL/min calculated using a standard Cockcroft-Gault formula (Cockroft & Gault, 1976) • For a female of childbearing potential (FCBP), a negative pregnancy test must be confirmed before enrolment. An FCBP must commit to take highly effective contraceptive precautions without interruption during the study and for 3, 6 or 12 months after the last dose of MOR00208, BEN or RTX respectively, whichever is later. An FCBP must refrain from breastfeeding and donating blood or oocytes during the course of the study and for 3, 6 or 12 months after the last dose of MOR00208, BEN or RTX respectively, whichever is later. Restrictions concerning blood donations apply as well to females who are not of childbearing potential. • Males must use an effective barrier method of contraception without interruption during the study and for 3, 6 or 12 months after the last dose of MOR00208, BEN or RTX respectively, whichever is later, if the patient is sexually active with an FCBP. Males must refrain from donating blood or sperm during study participation and for 3, 6 or 12 months after the last dose of MOR00208, BEN or RTX respectively, whichever is later. • In the opinion of the investigator, the patients must: • be able to comply with all study-related procedures, medication use, and evaluations • be able to understand and give informed consent • not be considered to be potentially unreliable and/or not cooperative.
Critères d'exclusion	• Patients who have: any other histological type of lymphoma including, e.g., primary mediastinal (thymic) large B-cell lymphoma (PMBL) or Burkitt's lymphoma, primary refractory DLBCL, patients with known "double/triple hit" DLBCL genetics, CNS lymphoma involvement in present or past medical history • Patients who had a major surgery less than 30 days prior to Day 1 dosing • Patients who have, within 14 days prior to Day 1 dosing: • not discontinued CD20-targeted therapy, chemotherapy, radiotherapy, investigational anticancer therapy or other lymphoma-specific therapy • received live vaccines • required parenteral antimicrobial therapy for active, intercurrent systemic infections • Patients who: • in the opinion of the investigator, have not recovered sufficiently from the adverse toxic effects of prior therapies, major surgeries or significant traumatic injuries • were previously treated with CD19-targeted therapy or BEN • have a history of previous severe allergic reactions to compounds of similar biological or chemical composition to MOR00208, RTX, murine proteins or BEN, or the excipients contained in the study drug formulations • have undergone ASCT within a period of ≤3 months prior to signing the informed consent form. Patients who have a more distant history of ASCT must exhibit full haematological recovery before enrolment into the study. • have undergone previous allogeneic stem cell transplantation • concurrently use other anticancer or experimental treatments Prior history of malignancies other than DLBCL, unless the patient has been free of the disease for ≥3 years prior to Screening. Exceptions to the ≥3-year time limit include history of the following: • incidental histological finding of prostate cancer (Tumour/Node/Metastasis [TNM] stage of T1a or T1b) • basal cell carcinoma of the skin • squamous cell carcinoma of the skin • carcinoma in situ of the cervix, breast and bladder • Patients with: • positive hepatitis B and/or C serology • known seropositivity for or history of active viral infection with HIV • evidence of active, severe uncontrolled systemic infections or sepsis • a history or evidence of severely immunocompromised state • a history or evidence of severe hepatic impairment (total serum bilirubin > 3 mg/dL), jaundice unless secondary to Gilbert's syndrome or documented liver involvement by lymphoma • a history or evidence of clinically significant cardiovascular, cerebrovascular, CNS and/or other disease that, in the investigator's opinion, would preclude participation in the study or compromise the patient's ability to give informed consent