Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	Un premier essai clinique chez l'humain, sans insu, d'escalade de dose pour évaluer la sécurité, la tolérabilité, la pharmacocinétique, la pharmacodynamique et la dose maximum tolérée et/ou recommandée de l'inhibiteur d'ATR, le BAY 1895344, chez des patients atteints de tumeurs solides avancées et de lymphomes.
Protocole ID	18594
ClinicalTrials.gov ID	NCT03188965
Type(s) de cancer	Tumeurs solides
Phase	Phase I
Type étude	Traitement
Médicament	BAY 1895344
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
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Statut	Fermé
But étude	The ATR(ataxia-telangiectasia and Rad3 related protein) inhibitor BAY1895344 is developed for the treatment of patients with advanced solid tumors and lymphomas. The purpose of the proposed trial is to evaluate the safety and tolerability of BAY1895344, and to identify the maximum tolerated dose of BAY1895344 that could be safely given to cancer patients. Further, the response of the cancer to the treatment will be determined.
Critères d'éligibilité	• Part A - single-agent dose-escalation part: Patients with histologically confirmed solid tumors or non-Hodgkin's lymphoma (NHL). • Part B - single-agent expansion part: • Patients with DNA Damage Response (DDR) defects or Mismatched Repair (MMR) deficiency putative biomarker-positive advanced solid tumors of the following histologies: i) castration-resistant prostate cancer (CRPC); ii) lung cancer, including adenocarcinoma, squamous carcinoma, or small cell lung cancer (SCLC); iii) colorectal cancer (CRC) and iv) gynecological tumors (ovarian cancer, endometrial cancer, or cervical cancer). • Patients with advanced mantle cell lymphoma (MCL). Patients with diffuse large B cell lymphoma (DLBCL) known to be positive for DDR defects. • Part C (dose escalation in combination with radium-223 dichloride) Castration-resistant prostate cancer with symptomatic bone metastases (positive bone scan the last 3 months) and no known visceral metastatic disease. • The following inclusion criteria apply to ALL (dose-escalation and expansion) patients: • Patients with tumors resistant or refractory to standard treatment and for which, in the opinion of the investigator, experimental treatment with BAY1895344 may be of benefit, or patients who refused standard treatment • Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1. • Adequate bone marrow function as assessed by the following laboratory tests • Part A + B: Hemoglobin (HB) >=8.5 g/dL; patients with chronic erythropoietin treatment consistent with institutional guidelines can be included Part C:Hemoglobin ≥9.0 g/dL • Platelet count >=100,000/mm*3 • Absolute neutrophil count (ANC) >=1500/mm*3

Critères d'exclusion	• Known hypersensitivity to the study drugs or excipients of the preparations or any agent given in association with this study • History of cardiac disease: congestive heart failure New York Heart Association (NYHA) class >II, unstable angina (angina symptoms at rest), new-onset angina (within the past 6 months before study entry), myocardial infarction within the past 6 months before study entry, or cardiac arrhythmias requiring anti-arrhythmic therapy (beta blockers, calcium channel blockers, and digoxin are permitted) • Moderate or severe hepatic impairment, i.e. Child-Pugh class B or C • Patients with known human immunodeficiency virus (HIV) infection • Patients who have an active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection requiring treatment. Patients with chronic HBV or HCV infection are eligible at the investigator's discretion provided that the disease is stable and sufficiently controlled under treatment. • Infections of CTCAE(Common Terminology Criteria for Adverse Events Version) Grade 2 not responding to therapy or active clinically serious infections of CTCAE Grade >2