Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	Étude de phase 2 sur l'olaparib en monothérapie chez des participants atteints d'un cancer de stade avancé présentant une mutation des gènes de réparation par recombinaison homologue (RRH) ou un déficit de recombinaison homologue (DRH) ayant déjà été traités.
Protocole ID	MK-7339-002
ClinicalTrials.gov ID	NCT03742895
Type(s) de cancer	Tumeurs solides
Phase	Phase II
Type étude	Traitement
Médicament	Olaparib
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
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Statut	Fermé
But étude	Cette étude évaluera l'efficacité et l'innocuité de l'olaparib en monothérapie chez des participants atteints de différents types de cancer de stade avancé (non résécable et/ou métastatique) : 1) dont la maladie a progressé ou qui sont intolérants au traitement standard; et 2) qui présentent une mutation des gènes de RRH ou un DRH.
Critères d'éligibilité	• Has a histologically- or cytologically-confirmed advanced (metastatic and/or unresectable) solid tumor (except breast or ovarian cancers whose tumor has a germline or somatic BRCA mutation) that is not eligible for curative treatment and for which standard of care therapy has failed. Participants must have progressed on or be intolerant to standard of care therapies that are known to provide clinical benefit. There is no limit on the number of prior treatment regimens. • Has either centrally-confirmed known or suspected deleterious mutations in at least 1 of the genes involved in HRR or centrally-confirmed HRD. • For participants receiving prior platinum (cisplatin, carboplatin, or oxaliplatin either as monotherapy or in combination) for advanced (metastatic and/or unresectable) solid tumor, have no evidence of disease progression during the platinum chemotherapy. • Has measurable disease per RECIST 1.1 or PCWG-modified RECIST 1.1 as assessed by the local site Investigator/radiology and confirmed by BICR. • Is able to provide a newly obtained core or excisional biopsy of a tumor lesion or either an archival formalin-fixed paraffin embedded (FFPE) tumor tissue block or slides. • Has a life expectancy of at least 3 months. • Has an Eastern Cooperative Oncology Group (ECOG) performance status of either 0 or 1, as assessed within 3 days of treatment initiation. • Male participants must agree to use contraception during the treatment period and for at least 90 days (3 months) after the last dose of study treatment and refrain from donating sperm during this period. • Female participants must not be pregnant or breastfeeding. Additionally, female participants must either not be a woman of childbearing potential (WOCBP) or, if a WOCBP, agree to use contraception during the treatment period and for at least 30 days (1 month) after the last dose of study treatment. • Has adequate organ function.

Critères d'exclusion	• Has a known additional malignancy that is progressing or has required active treatment in the last 5 years. Note: Participants with basal cell carcinoma of the skin, squamous cell carcinoma of the skin, ductal carcinoma in situ, or cervical carcinoma in situ that has undergone potentially curative therapy are not excluded. • Has myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML) or with features suggestive of MDS/AML. • Has known central nervous system (CNS) metastases and/or carcinomatous meningitis. Note: Participants with previously treated brain metastases may participate if radiologically stable, clinically stable, and without requirement for steroid treatment for at least 14 days prior to the first dose of study treatment. • Has received colony-stimulating factors (e.g., granulocyte colony-stimulating factor [G-CSF], granulocyte-macrophage colony-stimulating factor [GM-CSF] or recombinant erythropoietin) within 28 days prior to the first dose of study treatment. • Has a known history of human immunodeficiency virus (HIV) infection. • Has known active hepatitis infection (i.e., Hepatitis B or C). • Is unable to swallow orally administered medication or has a gastrointestinal disorder affecting absorption (e.g., gastrectomy, partial bowel obstruction, malabsorption). • Has received prior therapy with olaparib or with any other polyadenosine 5' diphosphoribose (poly[ADP ribose]) polymerization (PARP) inhibitor. • Has a known hypersensitivity to the components or excipients in olaparib. • Has received previous allogenic bone-marrow transplant or double umbilical cord transplantation (dUCBT). • Has received a whole blood transfusion in the last 120 days prior to entry to the study. Packed red blood cells and platelet transfusions are acceptable if not performed within 28 days of the first dose of study treatment.