Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	A Modular Phase I/IIa, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Efficacy of Ascending Doses of AZD5305 as Monotherapy and in Combination With Anti-cancer Agents in Patients With Advanced Solid Malignancies
Protocole ID	PETRA
ClinicalTrials.gov ID	NCT04644068
Type(s) de cancer	Tumeurs solides
Phase	Phase I-II
Type étude	Clinique
Médicament	AZD5305 en monothérapie et en association avec d'autres agents antinéoplasiques
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL H HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dre Susie Lau
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Statut	Actif en recrutement
But étude	This research is designed to determine if experimental treatment with PARP inhibitor, AZD5305, alone, or in combination with anti-cancer agents is safe, tolerable, and has anti-cancer activity in patients with advanced solid tumors.
Critères d'éligibilité	• Age ≥ 18 at the time of screening • Histological or cytological confirmation of advanced malignancy considered to be suitable for study treatment and meeting module specific eligibility criteria.. • Eastern Cooperative Oncology Group Performance status (ECOG PS: 0-2) • Life expectancy ≥ 12 weeks • Progressive cancer at the time of study entry • Patients must have evaluable disease as defined in module-specific criteria for Part A and Part B • Adequate organ and marrow function as defined by the protocol. • For Part B expansion cohorts: Provision of formalin-fixed and paraffin embedded (FFPE) tumour specimen is mandatory, where available, except if stated that it is optional in a specific Module. For Part A: - Patients may have received up to one prior line of therapy with a PARPi-based regimen (either as a treatment or as maintenance)For Part B: - Patients must not have received prior therapy with a PARPi-based regimen (either as a treatment or as maintenance).
Critères d'exclusion	• Treatment with any of the following: • Nitrosourea or mitomycin C within 6 weeks of the first dose of study treatment • Any investigational agents or study drugs from a previous clinical study within 5 half-lives or 3 weeks (whichever is shorter) of the first dose of study treatment • Any other chemotherapy, immunotherapy or anticancer agents within 3 weeks of the first dose of study treatment • Any live virus or bacterial vaccine within 28 days of the first dose of study treatment • Concomitant use of medications or herbal supplements known to be cytochrome P450 3A4 (CYP3A4) strong and moderate inhibitors or inducers. • Concomitant use of drugs that are known to prolong or shorten QT and have a known risk of

Torsades de Pointes.
- Receiving continuous corticosteroids at a dose of >10 mg prednisone/day or equivalent for any reason.
- Major surgery within 4 weeks of the first dose of study treatment.
- Radiotherapy with a wide field of radiation within 4 weeks or radiotherapy with a limited field of radiation for palliation within 2 weeks of the first dose of study treatment.
- Any history of persisting (> 2 weeks) severe pancytopenia due to any cause
- Spinal cord compression or brain metastases unless asymptomatic, treated and stable and not requiring continuous corticosteroids at a dose of >10mg prednisone/day or equivalent for at least 4 weeks prior to start of study treatment. Patients with leptomeningeal carcinomatosis are excluded.
- Cardiac conditions as defined by the clinical study protocol
- Other cardiovascular diseases as defined by any of the following:
- Symptomatic heart failure,
- uncontrolled hypertension,
- hypertensive heart disease with significant left ventricular hypertrophy
- acute coronary syndrome (ACS)/acute myocardial infarction (AMI), unstable angina pectoris, coronary intervention procedure with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) within 6 months.
- cardiomyopathy of any etiology
- presence of clinically significant valvular heart disease
- history of atrial or ventricular arrhythmia requiring treatment.
- subjects with atrial fibrillation and optimally controlled ventricular rate are permitted
- transient ischaemic attack, or stroke within 6 months prior to screening
- patients with symptomatic hypotension at screening
- Patients with myelodysplastic syndrome/acute myeloid leukaemia or with features suggestive of myelodysplastic syndrome (MDS)/acute myeloid leukaemia (AML).
- Refractory nausea and vomiting, chronic gastrointestinal diseases, inability to swallow the formulated product or previous significant bowel resection that would preclude adequate absorption of AZD5305
- Known allergy or hypersensitivity to investigational product(s) or any of the excipients of the investigational product(s).
- other module-specific criteria may apply