



Essai Clinique

Généré le 17 mai 2025 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	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Diane Provencher
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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	<ul style="list-style-type: none">• 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. <p>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)</p> <p>For Part B: - Patients must not have received prior therapy with a PARPi-based regimen (either as a treatment or as maintenance).</p>
Critères d'exclusion	<ul style="list-style-type: none">• 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