Essai Clinique

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Titre	Étude multicentrique de phase IIIb, à bras unique, ouverte, de l'olaparib administré en monothérapie dans le traitement du cancer du sein métastatique HER2 négative (HER2-) associé avec des mutations germinales des gènes de susceptibilité BRCA1/2.
Protocole ID	LUCY (D0816C00018)
ClinicalTrials.gov ID	NCT03286842
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Traitement
Médicament	Olaparib
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Ville	Québec
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Statut	Fermé
But étude	This open label, multi-centre phase IIIb study will assess the effectiveness, benefits and potential harms in the use of olaparib monotherapy treatment for patients with HER2-ve metastatic breast cancer associated with Germline breast cancer susceptibility gene (gBRCA1/2) mutations.
Critères d'éligibilité	• Provision of informed consent prior to any study specific procedures. For patients aged <20 years and screened in Japan, a written informed consent should be obtained from the patient and his or her legally acceptable representative. • Patients must be ≥18 years of age. • Histologically or cytologically confirmed HER2-ve breast cancer with evidence of metastatic disease. Patients can have either TNBC (defined as oestrogen receptor and progesterone receptor negative [immunohistochemistry nuclear staining <1%] and HER2-ve [immunohistochemistry 0, 1+ or 2+ and/or in situ hybridization non-amplified with ratio less than 2.0]) or oestrogen receptor / progesterone receptor positive breast cancer as long as they are HER2-ve. • Documented BRCA1/2 (+ve) status, the patient must have a mutation that is predicted to be deleterious or suspected deleterious (known or predicted to be detrimental / lead to loss of function). Mutations that are not clearly pathogenic will be assessed by a committee of genetic specialists to adjudicate if the patient is eligible. • Patients must have received a taxane or an anthracycline in either an adjuvant (may include neoadjuvant) or metastatic treatment setting. • Patients must not have received more than one prior line of chemotherapy in the metastatic setting. If a patient has oestrogen receptor and/or progesterone receptor positive HER2 negative metastatic breast cancer and has completed a prior line of hormonal treatment, then if the current or currently planned choice of treatment for the patient does not include a hormonal treatment then they would be a suitable patient to enter the study. Previous endocrine therapy could be in either an adjuvant or a metastatic setting and include endocrine therapy in combination with a targeted agent such as a CDK4/6 or mTOR inhibitor. • Be considered suitable, by the Investigator, for further treatment with single-agent chemotherapy for the metastatic disease. • Patients must have a life expectancy ≥ 16 weeks.

Critères d'exclusion	• Previous enrolment in the present study. • Participation in another clinical study with an investigational product (IP) during the last 1 month. • Patients receiving any systemic chemotherapy or radiotherapy (except for palliative reasons) within 3 weeks prior to study treatment. • Any previous treatment with a PARP inhibitor, including olaparib. • Other malignancy within the last 5 years except: any breast cancer not considered HER2 -ve/gBRCAm, adequately treated non-melanoma skin cancer, curatively treated in situ cancer of the cervix, ductal carcinoma in situ (DCIS), stage 1, grade 1 endometrial carcinoma, or other solid tumours including lymphomas (without bone marrow involvement) curatively treated with no evidence of disease for ≥5 years. • Resting electrocardiogram (ECG) with corrected QT interval (QTc) > 470 msec on two or more time points within a 24-hour period or family history of long QT syndrome. • Concomitant use of known strong (e.g., phenobarbital, enzalutamide, phenytoin, rifampicin, rifabutin, rifapentine, carbamazepine, nevirapine and St John's Wort) or moderate CYP3A inducers (e.g., bosentan, efavirenz, modafinil). The required washout period prior to starting olaparib is 5 weeks for enzalutamide or phenobarbital and 3 weeks for other agents. • Patients with myelodysplastic syndrome (MDS)/acute myeloid leukaemia (AML) or with features suggestive of MDS/AML. • Patients with symptomatic uncontrolled brain metastases. Patients with previously treated stable brain metastases are eligible. • Patients with known active hepatitis (B or C) due to risk of transmitting the infection through blood or other body fluids. • Previous allogenic bone marrow transplant or double umbilical cord blood transplantation (dUCBT). • Whole blood transfusions in the last 120 days prior to entry to the study (packed red blood cells and platelet transfusions are acceptable).