Essai Clinique

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Titre	PALbociclib CoLlaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy Alone for Hormone Receptor Positive (HR+) / Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Early Breast Cancer
Protocole ID	(CCTG) MA.37/PALLAS
ClinicalTrials.gov ID	NCT02513394
Type(s) de cancer	Sein
Phase	Phase III
Stade	Adjuvant
Type étude	Traitement
Médicament	Palbociclib et hormonothérapie
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
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Statut	Fermé
But étude	This is a prospective, two arm, international, multicenter, randomized, open-label Phase III study evaluating the addition of 2 years of palbociclib to standard adjuvant endocrine therapy for patients with HR+ / HER2- early breast cancer (EBC)The purpose of the PALLAS study is to determine whether the addition of palbociclib to adjuvant endocrine therapy will improve outcomes over endocrine therapy alone for HR+/HER2- early breast cancer. Assessment of a variety of correlative analysis, including evaluation of the effect of palbociclib in genomically defined tumor subgroups, is planned.
Critères d'éligibilité	• Signed informed consent prior to study specific procedures. • Age ≥18 years (or per national guidelines). • Pre- and postmenopausal women or men with Stage II (Stage IIA limited to max. 1000 patients) or Stage III early invasive breast cancer • Patients with multicentric and/or multifocal and/or bilateral early invasive breast cancer are eligible if all histopathologically examined tumors meet pathologic criteria for ER+ and/or PR+ and HER2-. • Patients must have histologically confirmed ER+ and/or PR+, HER2-, early invasive breast cancer. • Patients must have undergone breast surgery for the current malignancy. FFPE tumor tissue block must be confirmed to be received at the central sample repository prior to randomization. • ECOG performance status 0-1. • Patients must be able and willing to swallow and retain oral medication. • Serum or urine pregnancy test must be negative in premenopausal women within 14 days of randomization, or in women with amenorrhea of less than 12 months at time of randomization. • Patients who received neo/adjuvant therapy must be after last dose of chemotherapy and/or biologic therapy and must have sufficient resolution of side effects. • Patients who received breast/axilla/post-mastectomy chest wall radiotherapy must be after last dose of radiotherapy and must have sufficient resolution of side effects. • Patients must have sufficient resolution of any surgical side effects (no active wound healing

	complications). • Patients must either be initiating or have already started adjuvant hormonal treatment. • Patients who already received neo/adjuvant endocrine therapy are eligible as long as they are enrolled within 12 months of initial histological diagnosis and after completing no more than 6 months of adjuvant endocrine therapy. • Absolute neutrophil count ≥ 1,500/μL • Platelets ≥ 100,000/ mm3 • Hemoglobin ≥ 10g/dL • Total serum bilirubin ≤ ULN; or total bilirubin ≤ 3.0 × ULN with direct bilirubin within normal range in patients with documented Gilbert's Syndrome. • Aspartate amino transferase (AST or SGOT) and alanine amino transferase (ALT or SGPT) ≤ 1.5 × institutional ULN. • Serum creatinine within normal institutional limits or creatinine clearance ≥ 60 mL/min/1.73 m2 for patients with serum creatinine levels above institutional ULN.
Critères d'exclusion	• Concurrent therapy with other Investigational Products. • Prior therapy with any CDK inhibitor. • Patients with Stage I or IV breast cancer are not eligible. • History of allergic reactions attributed to compounds of chemical or biologic composition similar to palbociclib. • Patients receiving any medications or substances that are potent inhibitors or inducers of • CYP3A isoenzymes within 7 days of randomization. • Uncontrolled intercurrent illness that would limit compliance with study requirements. • Pregnant women, or women of childbearing potential without a negative pregnancy test within 14 days prior to randomization. • Patients with a history of any malignancy are ineligible • Patients who previously received endocrine therapy within 5 years prior to diagnosis of the current malignancy. • Patients on combination antiretroviral therapy. • Patients with clinically significant history of any liver disease. • Patients receiving concurrent exogenous hormone therapy (topical vaginal estrogen therapy is allowable).