# Essai Clinique

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| Titre | Étude de phase IIIb, ouverte et multicentrique évaluant l'innocuité et l'efficacité du ribociclib (LEE011) en association avec le létrozole dans le traitement d'hommes et de femmes pré/post-ménopausées atteints de cancer du sein avancé à récepteurs hormonaux positifs (HR+) et HER2-négatif (HER2 -) n'ayant reçu aucune hormonothérapie antérieure au stade avancé de la maladie (COMPLEEMENT-1). |
| Protocole ID | CLEE011A2404 |
| ClinicalTrials.gov ID | NCT02941926 |
| Type(s) de cancer | Sein |
| Phase | Phase III |
| Stade | Métastatique |
| Type étude | Traitement |
| Médicament | letrozole + ribociclib |
| Institution | CHU DE QUEBEC – UNIVERSITE LAVAL<br>HOPITAL DU SAINT-SACREMENT<br>1050 Ch Ste-Foy, Québec, QC, G1S 4L8 |
| Ville | Québec |
| Investigateur principal | Dre Christine Desbiens |
| Coordonnateur | Nathalie Carmichael<br>418-682-7511 poste 4551 |
| Statut | Fermé |
| But étude | The purpose of this Phase IIIb study is to collect additional safety and efficacy data for the combination of ribociclib + letrozole in men and pre/postmenopausal women with HR+HER2- advanced breast cancer. |
| Critères d'éligibilité | • Male or female advanced (locoregionally recurrent or metastatic) breast cancer not amenable to curative therapy.<br>• In the case of women, both pre/perimenopausal and postmenopausal patients are allowed to be included in this study; menopausal status is relevant for the requirement of goserelin to be used concomitantly with ribociclib and letrozole.<br>• Postmenopausal status is defined either by: I). Prior bilateral oophorectomy OR ii). Age ≥ 60 OR iii). Age < 60 and amenorrhea for 12 or more months (in the absence of chemotherapy, tamoxifen, toremifen, or ovarian suppression) and FSH and estradiol in the postmenopausal range per local normal range. If patient is taking tamoxifen or toremifene and age < 60, then FSH and plasma estradiol levels should be in post-menopausal range per local normal range. Note: For women with therapy-induced amenorrhea, serial measurements of FSH and/or estradiol are needed to ensure menopausal status.<br>• Premenopausal status is defined as either: I). Patient had last menstrual period within the last 12 months, OR ii). If on tamoxifen or toremifene within the past 14 days, plasma estradiol and FSH must be in the premenopausal range per local normal range, OR iii). In case of therapy induced amenorrhea, plasma estradiol and/or FSH must be in the premenopausal range per local normal range.<br>• Perimenopausal status is define as neither premenopausal nor postmenopausal Note: Throughout this document, perimenopausal and premenopausal status is grouped together and referred as "Premenopausal"<br>• Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer by local laboratory.<br>• Patient has HER2-negative breast cancer defined as a negative in situ hybridization test or an IHC status of 0, 1+ or 2+. If IHC is 2+, a negative in situ hybridization (FISH, CISH, or SISH) |

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| | test is required by local laboratory testing.<br>• Patient has an Eastern Cooperative Oncology Group (ECOG) performance status ≤2<br>• Patient has adequate bone marrow and organ function as defined by ALL of the following laboratory values (as assessed by local laboratory):<br>• Absolute neutrophil count ≥ 1.5 × 10^9/L<br>• Platelets ≥ 100 × 10^9/L<br>• Hemoglobin ≥ 9.0 g/dL<br>• Potassium, sodium, calcium corrected for serum albumin and magnesium within normal limits or corrected to within normal limits with supplements before first dose of the study medication<br>• INR ≤1.5<br>• Serum creatinine <1.5 mg/dl or creatinine clearance≥50 mL/min<br>• In absence of liver metastases, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) should be below 2.5 × ULN. If the patient has liver metastases, ALT and AST should be < 5 × ULN.<br>• Total serum bilirubin < ULN; or total bilirubin ≤ 3.0 × ULN with direct bilirubin within normal range in patients with well-documented Gilbert's Syndrome<br>• Patient must have a 12-lead ECG with ALL of the following parameters at screening:<br>• QTcF interval at screening <450 msec (using Fridericia's correction)<br>• Resting heart rate ≥ 50 bpm |
| Critères d'exclusion | • Patient who received any CDK4/6 inhibitor<br>• Patient who received any prior systemic hormonal therapy for advanced breast cancer; no more than one prior regimen of chemotherapy for the treatment of metastatic disease is permitted |