# Essai Clinique

Généré le 06 mai 2024 à partir de

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| Titre | Un essai de phase III, multicentrique, randomisé et sans-insu pour évaluer l'efficacité et la sécurité de ribociclib avec endocrinothérapie comme traitement adjuvant pour les patients avec récepteurs hormonaux positifs, HER2-négatif, cancer du sein précoce (nouvel essai adjuvant avec ribociclib [LEE011] : NATALEE) |
| Protocole ID | NATALEE |
| ClinicalTrials.gov ID | NCT03701334 |
| Type(s) de cancer | Sein |
| Phase | Phase III |
| Type étude | Traitement |
| Médicament | Ribociclib avec hormonothérapie |
| Institution | CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL<br>HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS<br>3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2 |
| Ville | Montréal |
| Investigateur principal | Dr Jean-François Boileau |
| Coordonnateur | Gabi Alexandru-Rolea<br>514-340-8222 poste 25526 |
| Statut | Fermé |
| But étude | A phase III multi-center, randomized, open-label trial to evaluate efficacy and safety of ribociclib with endocrine therapy as adjuvant treatment in patients with HR+/HER2- Early Breast Cancer |
| Critères d'éligibilité | • Patient is ≥ 18 years-old at the time of PICF signature<br>• Patient is female with known menopausal status at the time of PICF signature or initiation of adjuvant ET (whichever occurs earlier), or male.<br>• Patient with histologically confirmed unilateral primary invasive adenocarcinoma of the breast with a date of initial cytologic or histologic diagnosis within 18 months prior to randomization.<br>• Patient has breast cancer that is positive for ER and/or PgR<br>• Patient has HER2-negative breast cancer<br>• Patient has available archival tumor tissue from the surgical specimen<br>• Patient after surgical resection where tumor was removed completely, with the final surgical specimen microscopic margins free from tumor, and who belongs to one of the following categories (anatomic stage group II or III)<br>• If indicated, patient has completed adjuvant and/or neoadjuvant chemotherapy according to the institutional guidelines<br>• If indicated, patient has completed adjuvant radiotherapy according to the institutional guidelines<br>• Patient has no contraindication for the adjuvant ET in the trial and is planned to be treated with ET for 5 years |
| Critères d'exclusion | • Patient has received any CDK4/6 inhibitor<br>• Patient has received prior treatment with tamoxifen, raloxifene or AIs for reduction in risk ("chemoprevention") of breast cancer and/or treatment for osteoporosis within the last 2 years prior to PICF signature<br>• Patient has received prior treatment with anthracyclines at cumulative doses of 450 mg/m² or more for doxorubicin, or 900 mg/m² or more for epirubicin. Patient with a known hypersensitivity to any of the excipients of ribociclib and/or ET<br>• Patient with distant metastases of breast cancer beyond regional lymph nodes (stage IV according to AJCC 8th edition) and/or evidence of recurrence after curative surgery. |

- Patient is concurrently using other anti-neoplastic therapy with the exception of adjuvant ET
- Patient has had major surgery, chemotherapy or radiotherapy within 14 days prior to randomization
- Patient has not recovered from clinical and laboratory acute toxicities related to prior anti-cancer therapies
- Patient has a concurrent invasive malignancy or a prior invasive malignancy whose treatment was completed within 2 years before PICF signature
- Patient has known HIV infection, Hepatitis B or C infection
- Clinically significant, uncontrolled heart disease and/or cardiac repolarization abnormality
- Patient is currently receiving any of the following substances within 7 days before randomization - Concomitant medications, herbal supplements, and/or fruits that are known as strong inhibitors or inducers of CYP3A4/5 or Medications that have a narrow therapeutic window and are predominantly metabolized through CYP3A4/5
- is currently receiving or has received systemic corticosteroids ≤ 2 weeks prior to starting trial treatment
- Patient has impairment of GI function or GI disease that may significantly alter the absorption of the oral trial treatments
- Patient has any other concurrent severe and/or uncontrolled medical condition that would, in the Investigator's judgment, cause unacceptable safety risks, contraindicate patient participation in the clinical trial or compromise compliance with the protocol
- Patient participated in another interventional study and received treatment with an investigational product (or used an investigational device) within 30 days prior to randomization or within 5 half-lives of the investigational product, whichever is longer.
- Pregnant or breast-feeding (lactating) women or women who plan to become pregnant or breast-feed during the trial.