# Essai Clinique

Généré le 03 mai 2024 à partir de

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| Titre | Étude de phase III, multicentrique, à double insu, à répartition aléatoire, contrôlée par placebo, évaluant l'efficacité et l'innocuité de l'association du GDC-9545 et du palbociclib par rapport à l'association du létrozole et du palbociclib chez les patients atteints d'un cancer du sein localement avancé ou métastatique positif pour les récepteurs des œstrogènes et négatif pour le récepteur 2 du facteur de croissance épidermique humain (HER2) |
| Protocole ID | BO41843 |
| ClinicalTrials.gov ID | NCT04546009 |
| Type(s) de cancer | Sein |
| Phase | Phase III |
| Stade | Maladie avancée ou métastatique |
| Type étude | Clinique |
| Médicament | GDC-9545 en association avec le Palbociclib versus Letrozole en association avec le Palbociclib |
| Institution | CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL |
| Ville | |
| Investigateur principal | Dre Danielle Charpentier |
| Coordonnateur | Ana Lydia Tkalec<br>514-890-8000 poste 14186 |
| Statut | Fermé |
| But étude | This Phase III, randomized, double-blind, placebo-controlled, multicenter study will evaluate the efficacy and safety of GDC-9545 combined with palbociclib compared with letrozole combined with palbociclib in patients with estrogen receptor (ER)-positive, human epidermal growth factor receptor-2 (HER2)-negative locally advanced (recurrent or progressed) or metastatic breast cancer. |
| Critères d'éligibilité | • For women who are premenopausal or perimenopausal and for men: treatment with approved LHRH agonist therapy for the duration of study treatment<br>• Locally advanced (recurrent or progressed) or metastatic adenocarcinoma of the breast, not amenable to treatment with curative intent<br>• Documented ER-positive tumor and HER2-negative tumor, assessed locally<br>• Patients who have bilateral breast cancers which are both ER-positive and HER2-negative can be included in the study because the metastases are suitably targeted by the study treatments. If patients have bilateral tumors which are of different biomarker status, then proof of the ER and HER2 status of the metastases is required for study entry<br>• No history of systemic anti-cancer therapy for locally advanced (recurrent or progressed) or metastatic disease<br>• Disease recurrence from early-stage breast cancer after standard adjuvant endocrine therapy meeting the protocol-defined criteria of having received at least 24 months of treatment without disease progression during treatment and a disease-free interval since the completion of treatment that was greater than 12 months<br>• Measurable disease as defined per RECIST v.1.1 or bone only disease which must have at least one predominantly lytic bone lesion confirmed by CT or MRI which can be followed<br>• Eastern Cooperative Oncology Group Performance Status 0-1<br>• Adequate organ function |

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| Critères d'exclusion | • Disease recurrence during or within 12 months of completing prior neoadjuvant or adjuvant treatment with an aromatase inhibitor (AI)<br>• Disease recurrence during or within 12 months of completing prior neoadjuvant or adjuvant treatment with any CDK4/6 inhibitor<br>• Prior treatment with a selective estrogen receptor degrader (SERD)<br>• Prior treatment with tamoxifen is permitted, provided the patient did not experience disease recurrence within the first 24 months of treatment with tamoxifen<br>• Treatment with any investigational therapy within 28 days prior to study treatment<br>• Advanced, symptomatic, visceral spread that is at risk of life-threatening complications<br>• Known active uncontrolled or symptomatic CNS metastases, carcinomatous meningitis, or leptomeningeal disease<br>• Active cardiac disease or history of cardiac dysfunction<br>• Pregnant or breastfeeding |