Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	A Trial to Assess the Safety, Pharmacodynamic Effects, Pharmacokinetics and Efficacy of the MNK Inhibitor Tomivosertib (eFT508) in Combination With Paclitaxel, Following a Run-in Period of Tomivosertib Monotherapy, in Patients With Advanced Breast Cancer
Protocole ID	TRIO036
ClinicalTrials.gov ID	NCT04261218
Type(s) de cancer	Sein
Phase	Phase I
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Tomivosertib en combinaison avec paclitaxel suivi de tomivosertib en monothérapie
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
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Statut	Fermé
But étude	This is a multicenter, open-label trial to evaluate the safety, pharmacodynamics (PD), pharmacokinetics (PK), and efficacy of tomivosertib in combination with paclitaxel in patients with advanced breast cancer (ABC) of any subtype. The trial will enroll up to 45 patients with an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0, 1, or 2 with any breast cancer (BC) subtype and at least one measurable lesion, for whom standard-of-care treatments are ineffective, not tolerated or were refused. All patients will be initially treated with tomivosertib for 14 days (referred as the run-in period). Once treatment samples are obtained, weekly paclitaxel will be added to the treatment regimen. Tumor assessments will be done at screening and then periodically throughout trial treatment. Patients will continue to receive trial treatment until progressive disease, as defined according to the Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, intolerable trial-treatment-related toxicity, consent withdrawal, or other criteria is met (defined within the trial protocol).
Critères d'éligibilité	
Critères d'exclusion	