Essai Clinique

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Titre	An Open-Label Study to Characterize the Incidence and Severity of Diarrhea in Patients With Early-Stage HER2+ Breast Cancer Treated With Neratinib and Intensive Loperamide Prophylaxis
Protocole ID	PUMA-NER-6201
ClinicalTrials.gov ID	NCT02400476
Type(s) de cancer	Sein
Phase	Phase II
Médicament	Intensive Loperamide
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
Investigateur principal	Dr Michael Thirlwell
Coordonnateur	Stelliana Moreno 514-934-1934 poste 43131
Statut	Fermé
But étude	An Open-Label Study to Characterize the Incidence and Severity of Diarrhea in Patients with Early-Stage HER2+ Breast Cancer Treated with Neratinib and Intensive Loperamide Prophylaxis

Critères d'éligibilité	• Aged ≥18 years at signing of informed consent
	• Histologically confirmed stage 1 through stage 3c primary adenocarcinoma of the breast
	• Documented HER2 overexpression or gene-amplified tumor by a validated approved method
	• Patients must have completed a course of prior adjuvant trastuzumab or experienced side effects that resulted in early discontinuation of trastuzumab that have since resolved
	• The last dose of trastuzumab must have been given >2 weeks and ≤1 year (365 days) from enrollment
	• Clinical and radiologic assessments that are negative for local or regional recurrence of disease or metastatic disease at the time of study entry, including
	  • Bone scan or positron emission tomography (PET) scan; required only if alkaline phosphatase (ALP) is ≥2 x upper limit of normal (ULN) and/or there are symptoms of metastatic bone disease. A confirmatory imaging study is required if the results from the bone scan are questionable
	  • Computed tomography (CT), magnetic resonance imaging (MRI) or ultrasound of the abdomen and chest; required only if aspartate aminotransferase (AST)/alanine aminotransferase (ALT) or ALP is ≥2 x ULN
	  • Chest radiograph
	• Left ventricular ejection fraction (LVEF) ≥50% measured by multiple-gated acquisition scan (MUGA) or echocardiogram (ECHO)
	• Eastern Cooperative Oncology Group (ECOG) status of 0 to 1
	• Negative β-human chorionic gonadotropin (hCG) pregnancy test for premenopausal women of reproductive capacity (those who are biologically capable of having children) and for women less than 12 months after menopause. [Women are considered postmenopausal if they are ≥12 months without menses, in the absence of endocrine or anti-endocrine therapies.]
	• Women of childbearing potential must agree and commit to the use of a highly effective non-hormonal method of contraception, ie, intrauterine device, bilateral tubal ligation, vasectomized partner, or abstinence (only when it is the preferred lifestyle of the patient), from the time of informed consent until 28 days after the last dose of the investigational products. Men and their female partners of childbearing potential must agree and commit to use a highly effective method of contraception (ie, any of the above methods or hormonal contraception associated with inhibition of ovulation) while on treatment and for 3 months after last dose of investigational products

	• Recovery (ie, to Grade 1 or baseline) from all clinically significant AEs related to prior therapies (excluding alopecia, neuropathy, and nail changes) • Provide written, informed consent to participate in the study and follow the study procedures
Critères d'exclusion	• Clinical or radiologic evidence of local or regional recurrence of disease or metastatic disease prior to or at the time of study entry • Currently receiving chemotherapy, radiation therapy, immunotherapy, or biotherapy for breast cancer • Major surgery within <30 days of starting treatment or received chemotherapy, investigational agents, or other cancer therapy, except hormonal therapy (eg, tamoxifen, aromatase inhibitors), <14 days prior to the initiation of investigational products • Active uncontrolled cardiac disease, including cardiomyopathy, congestive heart failure (New York Heart Association functional classification of ≥2; including individuals who currently use digitalis, beta -blockers, or calcium channel blockers specifically for congestive heart failure), unstable angina, myocardial infarction within 12 months of enrollment, or ventricular arrhythmia • QTc interval >0.450 seconds (males) or >0.470 (females), or known history of QTc prolongation or Torsade de Pointes (TdP) • Screening laboratory assessments outside the following limits: Absolute neutrophil count (ANC) <1,000/µl (<1.0 x 109/L) Platelet count <100,000/µl (<100 x 109/L) Hemoglobin <9 g/dL Total bilirubin >1.5 x institutional upper limit of normal (ULN) (i n case of known Gilbert's syndrome, <2 x ULN is allowed) Creatinine Creatinine clearance <30 mL/min (as calculated by Cockcroft-Gault formula or Modification of Diet in Renal Disease [MDRD] formula) • Active, unresolved infections • Patients with a second malignancy, other than adequately treated non-melanoma skin cancers, in situ melanoma or in situ cervical cancer. Patients with other non-mammary malignancies must have been disease-free for at least 5years • Currently pregnant or breast-feeding • Significant chronic gastrointestinal disorder with diarrhea as a major symptom (eg, Crohn's disease, malabsorption, or Grade ≥2 National Cancer Institute [NCI] Common Terminology Criteria for Adverse Events Version 4.0 [CTCAE v.4.0] diarrhea of any etiology at baseline) • Clinically active infection with hepatitis B or hepatitis C virus • Evidence of significant medical illness, abnormal laboratory finding, or psychiatric illness/social situations that could, in the Investigator's judgment, make the patient inappropriate for this study • Known hypersensitivity to any component of the investigational products; known hypersensitivity to salicylates; known hypersensitivity to aspartame-containing products for patients with phenylketonuria; known allergies to any of the medications or components of medications used in the trial • Unable or unwilling to swallow tablets