Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Phase 2 Randomized, Double-Blinded, Controlled Study of Tucatinib vs Placebo in Combination With Capecitabine and Trastuzumab in Patients With Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma
Protocole ID	HER2CLIMB
ClinicalTrials.gov ID	NCT02614794
Type(s) de cancer	Sein
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Tucatinib
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
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Statut	Fermé
But étude	The purpose of this study is to assess the effect of tucatinib vs. placebo in combination with capecitabine and trastuzumab on progression-free survival (PFS) per RECIST 1.1 based on independent central review.
Critères d'éligibilité	• Histologically confirmed HER2+ breast carcinoma, with HER2+ defined by in situ hybridization (ISH) or fluorescence in situ hybridization (FISH) methodology • Received previous treatment with trastuzumab, pertuzumab, and T-DM1 • Progression of unresectable locally advanced or metastatic breast cancer after last systemic therapy (as confirmed by investigator), or be intolerant of last systemic therapy • Have measurable or non-measurable disease assessable by RECIST 1.1 • Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 • Adequate hepatic and renal function • Left ventricular ejection fraction (LVEF) ≥ 50% • CNS Inclusion - Based on screening brain magnetic resonance imaging (MRI), patients must have one of the following: • No evidence of brain metastases • Untreated brain metastases not needing immediate local therapy • Previously treated brain metastases not needing immediate local therapy • Brain metastases previously treated with local therapy may either be stable since treatment or may have progressed since prior local CNS therapy • Patients treated with CNS local therapy for newly identified lesions found on contrast brain MRI performed during screening for this study may be eligible to enroll if the following criteria are met: • Time since whole brain radiation therapy (WBRT) is ≥ 21 days prior to first dose of study treatment, time since stereotactic radiosurgery (SRS) is ≥ 7 days prior to first dose of study treatment, or time since surgical resection is ≥ 28 days. • Other sites of disease assessable by RECIST 1.1 are present • Relevant records of any CNS treatment must be available to allow for classification of target and non-target lesions

Critères d'exclusion	• Previously been treated with: • lapatinib within 12 months of starting study treatment (except in cases where lapatinib was given for ≤ 21 days and was discontinued for reasons other than disease progression or toxicity) • neratinib, afatinib, or other investigational HER2/epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) at any time previously • capecitabine (or other fluoropyrimidine) for metastatic disease except in cases where capecitabine was given for < 21 days and was discontinued for reasons other than disease progression or toxicity. Patients who have received capecitabine for adjuvant or neoadjuvant treatment at least 12 months prior to starting study treatment are eligible. • Clinically significant cardiopulmonary disease • Carriers of Hepatitis B or Hepatitis C or have other known chronic liver disease • Positive for human immunodeficiency virus (HIV) • Unable for any reason to undergo MRI of the brain • Have used a strong CYP3A4 or CYP2C8 inhibitor within 5 half-lives of the inhibitor, or a strong CYP3A4 or CYP2C8 inducer within 5 days prior to first dose of study treatment • CNS Exclusion - Based on screening brain MRI, patients must not have any of the following: • Any untreated brain lesions > 2.0 cm in size, unless approved by medical monitor • Ongoing use of systemic corticosteroids for control of symptoms of brain metastases at a total daily dose of > 2 mg of dexamethasone (or equivalent) • Any brain lesion thought to require immediate local therapy. Patients who undergo local treatment for such lesions identified by screening contrast brain MRI may still be eligible for the study based on criteria described under CNS inclusion criteria • Known or suspected leptomeningeal disease (LMD) • Poorly controlled seizures