Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Phase 2a Study of ZW25 in Combination With Palbociclib Plus Fulvestrant
Protocole ID	ZWI-ZW25-202
ClinicalTrials.gov ID	NCT04224272
Type(s) de cancer	Sein
Phase	Phase II
Type étude	Clinique
Médicament	ZW25 en association avec palbociclib + fulvestrant
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
Ville	
Investigateur principal	Dr Cristiano Ferrario
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Statut	Fermé
But étude	This is a multicenter, Phase 2a, open-label, 2-part study to investigate the safety, tolerability, and anti-tumor activity of ZW25 (zanidatamab) in combination with palbociclib plus fulvestrant. Eligible patients include those with locally advanced (unresectable) and/or metastatic human epidermal growth factor receptor 2 (HER2)-positive, hormone receptor (HR)-positive breast cancer.
Critères d'éligibilité	• Pathologically-confirmed diagnosis of breast cancer with evidence of locally advanced (unresectable) and/or metastatic disease. All patients in both Parts 1 and 2 must have HER2-positive and HR-positive disease. • Received prior treatment with trastuzumab, pertuzumab, AND ado-trastuzumab emtansine (T-DM1); disease progression during or after the most recent prior therapy. Patients in any part of the study who did not receive pertuzumab or T-DM1 because of lack of access (e.g., due to insurance coverage or because they were treated prior to regulatory agency approval of the agent in a relevant indication) or due to medical ineligibility for treatment with T-DM1 (e.g., history of severe infusion reactions to trastuzumab, >/= Grade 2 peripheral neuropathy, or platelet count < 100 x 10^9/L) may be eligible for the study. Prior treatment with endocrine therapy in the neoadjuvant, adjuvant, and/or metastatic setting is permitted. • Sites of disease assessible per RECIST version 1.1 (both measurable and non-measurable disease allowed) • An Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0 or 1 • Adequate organ function • Adequate cardiac left ventricular function, as defined by left ventricular ejection fraction (LVEF) >/= institutional standard of normal
Critères d'exclusion	• Prior treatment with trastuzumab, pertuzumab, lapatinib, T-DM1, or other anti-HER2-targeted therapy • Prior treatment with chemotherapy, other anti-cancer therapy not otherwise specified, or hormonal cancer therapy • Prior treatment with palbociclib or any other CDK4/6 inhibitor, including experimental agents • History of myocardial infarction or unstable angina within 6 months prior to enrollment, troponin levels consistent with myocardial infarction, or clinically significant cardiac disease, such as ventricular arrhythmia requiring therapy, uncontrolled hypertension, or any history of symptomatic congestive heart failure (CHF)

- QTc Fridericia (QTcF) > 470 ms
- Grade 2 or greater pneumonitis and/or interstitial lung disease, including pulmonary fibrosis, or other clinically significant infiltrative pulmonary disease not related to lung metastases
- Active hepatitis B or hepatitis C infection
- Acute or chronic uncontrolled renal disease, pancreatitis, or severe liver disease (Child-Pugh Class C)
- Known infection with Human Immunodeficiency Virus (HIV)-1 or HIV-2 (Exception: patients with well controlled-HIV [e.g., cluster of differentiation 4 (CD4)-positive T-cell count > 350 mm3 and undetectable viral load] are eligible.)
- Prior or concurrent malignancy whose natural history or treatment has the potential to interfere with the safety or efficacy assessment of the investigational regimen
- Brain metastases: Untreated central nervous system (CNS) metastases, symptomatic CNS metastases, or radiation treatment for CNS metastases within 4 weeks of start of study treatment. Stable, treated brain metastases are allowed (defined as patients who are off steroids and anticonvulsants and are neurologically stable for at least 1 month at the time of screening).
- History of or ongoing leptomeningeal disease
- Grade 3 or greater peripheral neuropathy