Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	A Phase IIIB, Multinational, Multicenter, Randomized, Open-Label Study to Evaluate Patient Preference for Home Administration of Fixed-Dose Combination of Pertuzumab and Trastuzumab for Subcutaneous Administration in Participants With Early or Locally Advanced/Inflammatory HER2-Positive Breast Cancer
Protocole ID	MO43110
ClinicalTrials.gov ID	NCT05415215
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Pertuzumab et Trastuzumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	
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Statut	Fermé
But étude	This is a Phase IIIb, multinational, multicenter, randomized, open-label study to evaluate patient preference of the fixed-dose combination of pertuzumab and trastuzumab for subcutaneous use (PH FDC SC) administration in the home setting compared with the hospital setting during the cross-over period of adjuvant treatment in participants with early or locally advanced/inflammatory human epidermal growth factor receptor 2-positive (HER2+) breast cancer.
Critères d'éligibilité	• Eastern Cooperative Oncology Group (ECOG) performance status 0-1 • Intact skin at planned site of subcutaneous (SC) injections • Left ventricular ejection fraction (LVEF) greater than or equal to (≥)55% by echocardiogram (ECHO) or multiple-gated acquisition scan (MUGA) • Negative human immunodeficiency virus (HIV) test at screening • Negative hepatitis B surface antigen (HBsAg) test at screening • Positive hepatitis B surface antibody (HBsAb) test at screening, or negative HBsAb at screening accompanied by either of the following: Negative total hepatitis B core antibody (HBcAb); Positive total HBcAb test followed by a negative (per local laboratory definition) hepatitis B virus (HBV) DNA test • Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening • For female participants of childbearing potential: agreement to remain abstinent or use contraception and agree to refrain from donating eggs during the treatment period and for 7 months after the final dose of the study treatment • For male participants: agreement to remain abstinent or use a condom, and agree to refrain from donating sperm during the treatment period and for 7 months after the final dose of study treatment Disease-specific Inclusion Criteria: • Female and male participants with stage II-IIIC early or locally advanced/inflammatory human epidermal growth factor receptor 2-positive (HER2+) breast cancer • Primary tumor >2 centimetres (cm) in diameter, or node-positive disease • HER2+ breast cancer confirmed by a local laboratory prior to study enrollment. HER2+ status

	will be determined based on pretreatment breast biopsy material and defined as 3+ by Immunohistochemistry (IHC) and/or positive by HER2 amplification by in situ hybridization (ISH) following American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines 2018 and updates (Wolff et al. Arch Pathol Lab Med 2018) • Hormone receptor status of the primary tumor determined by local assessment following American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines and updates (Allison et al. J Clin Oncol 2020) • Agreement to undergo mastectomy or breast conserving surgery after neoadjuvant therapy, including the axillary nodes • Availability of formalin-fixed, paraffin-embedded (FFPE) tumor tissue block for local confirmation of HER2 and hormone receptor status following current ASCO/CAP guidelines Inclusion Criteria for Treatment with Adjuvant PH FDC SC: • Completed the neoadjuvant phase of this study and underwent surgery, and achieved pathologic complete response (pCR), defined as eradication of invasive disease in the breast and axilla according to the current American Joint Committee on Cancer (AJCC) staging system classification, and using the resected specimen by the local pathologist on the basis of guidelines to be provided in a pathology manual • Adequate wound healing after breast cancer surgery per investigator's assessment to allow initiation of study treatment within less than or equal to (≤)9 weeks of last systemic neoadjuvant therapy
Critères d'exclusion	• Stage IV (metastatic) breast cancer • History of concurrent or previously treated non-breast malignancies, except for appropriately treated 1) non-melanoma skin cancer and/or 2) in situ carcinomas, including cervix, colon, and skin. A participant with previous invasive non-breast cancer is eligible provided he/she has been disease free for more than 5 years • Participants who are pregnant or breastfeeding or intending to become pregnant during the study or within 7 months after the final dose of study treatments • Treatment with investigational therapy within 28 days prior to initiation of study treatment • Active, unresolved infections at screening requiring treatment • Participants who may have had a recent episode of thromboembolism and are still trying to optimize the anticoagulation dose and/or have not normalized their International Normalized Ratio (INR) • Serious cardiac illness or medical conditions • History of ventricular dysrhythmias or risk factors for ventricular dysrhythmias • Inadequate bone marrow function • Impaired liver function • Renal function with creatinine clearance <50 mL/min using the Cockroft-Gault formula and serum creatinine >1.5x upper limit of normal (ULN) • Major surgical procedure unrelated to breast cancer within 28 days prior to study entry or anticipation of the need for major surgery during the course of study treatment • Current severe, uncontrolled systemic disease that may interfere with planned treatment • Any serious medical condition or abnormality in clinical laboratory tests that precludes an individual's safe participation in and completion of the study • Known active liver disease, for example, active viral hepatitis infection, autoimmune hepatic disorders, or sclerosing cholangitis • Known hypersensitivity to any of the study drugs, excipients, and/or murine proteins or a history of severe allergic or immunological reactions, e.g., difficult to control asthma • Current chronic daily treatment with corticosteroids • Assessment by the investigator as being unable or unwilling to comply with the requirements of the protocol Cancer-specific Exclusion Criteria for Neoadjuvant Phase: • Participants who have received any previous systemic therapy for treatment or prevention of breast cancer, or radiation therapy for the treatment of cancer • Participants who have a past history of ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS) if they have received any systemic therapy for its treatment or radiation therapy to the ipsi- or contralateral breast cancer • Participants with high-risk for breast cancer who have received chemopreventive drugs in the past • Participants with multicentric breast cancer, unless all tumors are HER2+ • Participants with bilateral breast cancer • Participants who have undergone an excisional biopsy of primary tumor and/or axillary lymph nodes • Axillary lymph node dissection (ALND) prior to initiation of neoadjuvant therapy • Sentinel lymph node biopsy (SLNB) prior to neoadjuvant therapy Exclusion Criterion for Treatment with Adjuvant Trastuzumab Emtansine (Arm E): • Current Grade ≥3 peripheral neuropathy (according to the NCI CTCAE v5.0)