Essai Clinique

Généré le 29 avr. 2024 à partir de

Titre	A Phase 3, Randomized, Multi-center, Open-label Study of Trastuzumab Deruxtecan (T-DXd) Versus Investigator's Choice Chemotherapy in HER2-Low, Hormone Receptor Positive Breast Cancer Patients Whose Disease Has Progressed on Endocrine Therapy in the Metastatic Setting
Protocole ID	DESTINY-Breast06
ClinicalTrials.gov ID	NCT04494425
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Trastuzumab Deruxtecan versus traitement au choix de l'investigateur
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE H HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
Investigateur principal	Dr Michel Pavic
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Statut	Fermé
But étude	This study will evaluate the efficacy, safety and tolerability of trastuzumab deruxtecan compared with investigator's choice chemotherapy in human epidermal growth factor receptor (HER)2-low, hormone receptor (HR) positive breast cancer patients whose disease has progressed on endocrine therapy in the metastatic setting.

Critères d'éligibilité	• Patients must be ≥18 years of age
	• Pathologically documented breast cancer that:
	  • is advanced or metastatic
	  • has a history of HER2-low or negative expression defined as IHC 2+/ISH- or IHC 1+ (ISH- or untested) or HER2 IHC 0 (ISH- or untested)
	  • has HER2-low or HER2 IHC >0 <1+ expression
	  • was never previously HER2-positive
	  • is documented HR+ disease in the metastatic setting.
	  • No prior chemotherapy for advanced or metastatic breast cancer.
	  • Has adequate tumor samples for assessment of HER2 status
	  • Must have either:
	  • disease progression within 6 months of starting first line metastatic treatment with an endocrine therapy combined with a CDK4/6 inhibitor or
	  • disease progression on at least 2 previous lines of endocrine therapy with or without a targeted therapy in the metastatic setting. Of note with regards to the ≥2 lines of previous ET requirement: disease recurrence while on the first 24 months of starting adjuvant ET, will be considered a line of therapy; these patients will only require 1 line of ET in the metastatic setting.
	  • Has protocol-defined adequate organ and bone marrow function

Critères d'exclusion	• Ineligible for all options in the investigator's choice chemotherapy arm • Lung-specific intercurrent clinically significant illnesses • Uncontrolled or significant cardiovascular disease or infection • Active or prior documented interstitial lung disease (ILD)/pneumonitis or suspected ILD/pneumonitis that cannot be ruled out by imaging at screening • Patients with spinal cord compression or clinically active central nervous system metastases • Prior randomization or treatment in a previous trastuzumab deruxtecan study regardless of treatment arm assignment