Essai Clinique

Généré le 29 mars 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	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Jamil Asselah
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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