Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Randomized, Controlled, Open Label, Phase III Study Evaluating the Efficacy and Safety of JDQ443 Versus Docetaxel in Previously Treated Subjects With Locally Advanced or Metastatic KRAS G12C Mutant Non-small Cell Lung Cancer
Protocole ID	KontRASt-02
ClinicalTrials.gov ID	NCT05132075
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	JDQ443 versus docétaxel
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Benjamin Shieh
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Statut	Actif en recrutement
Date d'activation	19-05-2023
But étude	This is a phase III open label study designed to compare JDQ443 as monotherapy to docetaxel in participants with advanced non-small cell lung cancer (NSCLC) harboring a KRAS G12C mutation who have been previously treated with a platinum-based chemotherapy and immune checkpoint inhibitor therapy either in sequence or in combination.
Critères d'éligibilité	• Participant has histologically confirmed locally advanced/metastatic (stage IIIB/IIIC or IV) • Participant has a KRAS G12C mutation present in tumor tissue prior to enrollment, as determined by a Novartis designated central laboratory. • Participants has received one prior platinum-based chemotherapy regimen and one prior immune checkpoint inhibitor therapy for locally advanced or metastatic disease • Participant has at least 1 evaluable (measurable or non-measurable) lesion by RECIST 1.1 at the screening visit.
Critères d'exclusion	• Participant has previously received docetaxel, KRAS G12C inhibitor or any other systemic therapy for their locally advanced or metastatic NSCLC other than one platinum-based chemotherapy and one prior immune check point inhibitor • Participant has EGFR-sensitizing mutation and/or ALK rearrangement by local laboratory testing. Participants with other druggable alterations will be excluded if required by local guidelines. • Participant has known active central nervous system (CNS) metastases and/or carcinomatous meningitis • Participant has an history of interstitial lung disease or pneumonitis grade > 1.

	Other inclusion/exclusion criteria may apply