Essai Clinique

Généré le 17 mai 2024 à partir de

Titre	Étude de phase Ib/II en ouvert, multicentrique, d'escalade de dose, évaluant le JDQ443 chez des patients atteints de tumeurs solides avancées présentant la mutation KRAS G12C
Protocole ID	KontRASt-01
ClinicalTrials.gov ID	NCT04699188
Type(s) de cancer	Tumeurs solides
Phase	Phase I-II
Type étude	Clinique
Médicament	JDQ443
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dr Mustapha Tehfé
Coordonnateur	Adeline Hamon 514-890-8000 poste 30737
Statut	Actif en recrutement
But étude	This is a phase Ib/II open label study. The escalation part will characterize the safety and tolerability of JDQ443 single agent and JDQ443 in combination with the other study treatments (TNO155 and spartalizumab) in advanced solid tumor patients. After the determination of the maximum tolerated dose / recommended dose for a particular treatment arm, dose expansion will assess the anti-tumor activity and further assess the safety, tolerability, and PK/PD of each regimen at the maximum tolerated dose / recommended dose.
Critères d'éligibilité	• Adult patients with advanced (metastatic or unresectable) KRAS G12C mutant solid tumors • Prior treatment with a KRAS G12C inhibitor may be allowed for dose escalations of combinations
Critères d'exclusion	• Tumors harboring driver mutations that have approved therapies or tumors with known activating KRAS, NRAS, HRAS, BRAF or PTPN11 (SHP2) mutations, with exception of KRAS G12C mutations • Active brain metastases • Clinically significant cardiac disease or risk factors at screening