Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Randomized, Double-blind, Placebo-controlled, Phase III Study Evaluating the Efficacy and Safety of Canakinumab in Combination With Docetaxel Versus Placebo in Combination With Docetaxel in Adult Subjects With Non-small Cell Lung Cancer (NSCLC) Previously Treated With PD-(L)1 Inhibitors and Platinum-based Chemotherapy
Protocole ID	CANOPY 2
ClinicalTrials.gov ID	NCT03626545
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Canakinumab avec Docetaxel
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Scott Owen
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Statut	Actif en recrutement
But étude	This phase III study is designed to evaluate the role of IL-1β inhibition in combination with docetaxel in subjects with advanced NSCLC previously treated with PD-(L)1 inhibitors and platinum-based chemotherapy. The randomized III part will be preceded by a safety run-in part in which the recommended dose of the combination of canakinumab and docetaxel will be confirmed.
Critères d'éligibilité	• Histologically confirmed advanced (stage IIIB) or metastatic NSCLC. • Subject has received one prior platinum-based chemotherapy and one prior PD-(L)1 inhibitor therapy for locally advanced or metastatic disease. • Subject with ECOG performance status (PS) of 0 or 1. • Subject with at least 1 evaluable (measurable or non-measurable) lesion by RECIST 1.1 in solid tumors criteria.
Critères d'exclusion	• Subject who previously received docetaxel, canakinumab (or another IL-1β inhibitor), or any systemic therapy for their locally advanced or metastatic NSCLC other than one platinum-based chemotherapy and one prior PD-(L)1 inhibitor. • Subject with EGFRor ALK positive tumor. • History of severe hypersensitivity reaction to monoclonal antibodies, taxanes or excipients of docetaxel or canakinumab. • Other protocol-defined inclusion/exclusion may apply.