Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	A Phase 2 Study Evaluating the Efficacy, Safety, Tolerability, and Pharmacokinetics of Tarlatamab in Subjects With Relapsed/Refractory Small Cell Lung Cancer After Two or More Prior Lines of Treatment
Protocole ID	20200491
ClinicalTrials.gov ID	NCT05060016
Type(s) de cancer	Poumon à petites cellules
Phase	Phase II
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Tarlatamab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
Investigateur principal	Dr Nicolas Marcoux
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Statut	Actif en recrutement
Date d'activation	29-09-2022
But étude	The main aim of this study is to: • evaluate safety and efficacy (per Response Evaluation Criteria in Solid Tumors version 1.1 [RECIST 1.1] by investigator) of 2 dose levels of Tarlatamab for Part 1 only • evaluate anti-tumor activity of Tarlatamab as determined by objective response rate (ORR) per RECIST 1.1 by blinded independent central review (BICR) for Part 1 and 2
Critères d'éligibilité	• Participant has provided informed consent/assent prior to initiation of any study specific activities/procedures. • Male and female participants ≥ 18 years of age (or legal adult age within country) at the time of signing the informed consent. • Histologically or cytologically confirmed relapsed/refractory SCLC • Participants who progressed or recurred following 1 platinum-based regimen and at least 1 other prior line of therapy • Eastern Cooperative Oncology Group (ECOG) performance status of 0 1. • Minimum life expectancy of 12 weeks. • Measurable lesions as defined per RECIST 1.1 within 21 days prior to the first dose of tarlatamab. • Participants with treated brain metastases are eligible provided they meet defined criteria.
Critères d'exclusion	Disease Related • Untreated or symptomatic brain metastases and leptomeningeal disease. • Has evidence of interstitial lung disease or active, non-infectious pneumonitis. • Participants who experienced recurrent pneumonitis (grade 2 or higher) or severe, life-threatening immune-mediated adverse events or infusion-related reactions including those that lead to permanent discontinuation while on treatment with immuno-oncology agents. • Unresolved toxicity from prior anti-tumor therapy, defined as per protocol.

Other Medical Conditions

- History of other malignancy within the past 2 years, with exceptions
- Myocardial infarction and/or symptomatic congestive heart failure (New York Heart Association > class II) within 12 months of first dose of tarlatamab.
- History of arterial thrombosis (eg, stroke or transient ischemic attack) within 12 months of first dose of tarlatamab.
- Presence of fungal, bacterial, viral, or other infection requiring oral or IV antimicrobials for management within 7 days of first dose of tarlatamab.
- Presence of any indwelling line or drain.
- History of hypophysitis or pituitary dysfunction.
- Exclusion of hepatitis infection based on the results and/or criteria per protocol.
- Major surgery within 28 days of first dose of tarlatamab.
- History or evidence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Subject is eligible if no acute symptoms of coronavirus disease 2019 (COVID-19) within 14 days prior to first dose of tarlatamab (counted from day of positive test for asymptomatic subjects).

Prior/Concomitant Therapy

- Participant received prior therapy with tarlatamab.
- Prior anti-cancer therapy within 28 days prior to first dose of tarlatamab.
- Has a diagnosis of immunodeficiency or is receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of tarlatamab.
- Live and live-attenuated vaccines within 4 weeks prior to the start off tarlatamab treatment.

Other Exclusions

- Female participants of childbearing potential unwilling to use protocol specified method of contraception during treatment and for an additional 72 days after the last dose of tarlatamab.
- Female participants who are breastfeeding or who plan to breastfeed while on study through 72 days after the last dose of tarlatamab.
- Female participants planning to become pregnant while on study through 72 days after the last dose of tarlatamab.
- Female participants of childbearing potential with a positive pregnancy test assessed at screening and/or day 1 by a highly sensitive urine or serum pregnancy test.
- Male participants with a female partner of childbearing potential who are unwilling to practice sexual abstinence (refrain from heterosexual intercourse) or use contraception during treatment and for an additional 132 days after the last dose of tarlatamab.
- Male participants with a pregnant partner who are unwilling to practice abstinence or use a condom during treatment and for an additional 132 days after the last dose of tarlatamab.
- Male participants unwilling to abstain from donating sperm during treatment and for an additional 132 days after the last dose of tarlatamab.
- Participant has known sensitivity to any of the products or components to be administered during dosing.
- Participant likely to not be available to complete all protocol-required study visits or procedures, and/or to comply with all required study procedures.
- History or evidence of any other clinically significant disorder, condition or disease determined by the investigator or Amgen physician.