B-FAST - (dernière mise à jour : 06/08/2019)

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Informations générales

Titre de l'étude : Etude multicentrique de phase II/III évaluant l'efficacité et la sécurité d'emploi de multiples thérapies ciblées chez des patients présentant un cancer du poumon non à petites cellules localement avancé ou métastatique, contenant des mutations somatiques actionnables détectées dans le sang

Traitement : Métastasique ou localement avancé

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : II/III **Stade** : Métastatique **Ligne(s)** : 1, 2, 3, 4

Schéma : This is a phase 2/3, global, multicenter, open-label, multi-cohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in combination in participants with unresectable, advanced or metastatic NSCLC determined to harbor oncogenic somatic mutations or positive by tumor mutational burden (TMB) assay as identified by two blood-based next-generation sequencing (NGS) circulating tumor DNA (ctDNA) assays.

6 cohorts:
- Cohort A: Alectinib 600 Milligrams (mg)
This cohort includes participants with anaplastic lymphoma kinase (ALK) positive NSCLC. Participants will receive alectinib 600 mg orally twice in a day (BID) until disease progression, unacceptable toxicity, withdrawal of consent or death.
- Cohort B: Dose Finding Phase (DFP) Alectinib
This cohort includes participants with rearranged during transfection (RET) positive NSCLC. Participants may receive alectinib 900 or 1200 mg orally BID until disease progression, unacceptable toxicity, withdrawal of consent or death if the recommended phase 2 dose (RP2D) is not established in any other clinical study. Participants may receive 750 mg or 600 mg, if it is unsafe to pursue the higher starting dose
- Cohort B: Dose Expansion Phase (DEP) Alectinib
This cohort includes participants with RET positive NSCLC. Participants will receive alectinib at the RP2D established in the DFP of Cohort B or a separate clinical study. Participants will continue receiving study treatment until disease progression, unacceptable toxicity, withdrawal of consent or death.
- Cohort C: Atezolizumab 1200 mg
This cohort includes participants with bTMB positive NSCLC. Participants will receive atezolizumab at a dose of 1200 mg administered by IV infusion every 21 days (Q21D) until disease progression, loss of clinical benefit, unacceptable toxicity, withdrawal of consent or death.
- Cohort C: Pemetrexed, Cisplatin or Carboplatin
This cohort includes participants with bTMB positive, non-squamous NSCLC. Participants will receive 4 or 6 cycles of treatment, with each cycle being 21 days in duration. Carboplatin at a dose of area under the concentration-time curve (AUC) of 5 or 6 IV or cisplatin at a dose of 75 milligrams per meter square (mg/m^2) IV on Day 1 of each cycle combined with pemetrexed at a dose of 500 mg/m^2 IV on Day 1 of each cycle. Pemetrexed may be continued as maintenance therapy every 21 days (Q21D) as per local standard of care.
- Cohort C: Gemcitabine, Cisplatin or Carboplatin
This cohort includes participants with bTMB positive, squamous NSCLC. Participants will receive 4 or 6 cycles of treatment, with each cycle being 21 days in duration. Gemcitabine 1250 mg/m^2 IV on Days 1 and 8 of every cycle and cisplatin 75 mg/m^2 IV on Day 1 Q21D or gemcitabine 1000 mg/m^2 IV on Days 1 and 8 of every cycle and carboplatin AUC 5 IV on Day 1 Q21D.

Spécialités / Localisations

Spécialité n°1 : Organes respiratoires et intrathoraciques

CIM10 - Localisation n°1 : **C34** - Tumeur maligne des bronches et du poumon

Critères

Critères d'inclusion : - Histologically or cytologically confirmed diagnosis of unresectable Stage IIIb not amenable to treatment with combined modality chemoradiation (advanced) or Stage IV (metastatic) NSCLC
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2
- Measurable disease
- Adequate recovery from most recent systemic or local treatment for cancer
- Adequate organ function
- Life expectancy greater than or equal to (>/=) 12 weeks
- For female participants of childbearing potential and male participants, willingness to use acceptable methods of contraception

Critères de non-inclusion : - Inability to swallow oral medication
- Women who are pregnant or lactating
- Active or untreated CNS metastases as determined by computed tomography (CT) or magnetic resonance imaging (MRI) evaluation during screening and prior radiographic assessments
- History of other malignancy within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, in situ ductal adenocarcinoma of the breast, in situ prostate cancer, limited stage bladder cancer, Stage I uterine cancer, or other cancers from which the patient has been disease-free for at least 2 years
- Significant cardiovascular disease, such as New York Heart Association cardiac disease (Class II or greater), myocardial infarction, or cerebrovascular accident within 3 months prior to randomization, unstable arrhythmias, or unstable angina
- Known human immunodeficiency virus (HIV) positivity or autoimmune deficiency syndrome (AIDS)-related illness
- Either a concurrent condition or history of a prior condition that places the patient at unacceptable risk if he/she were treated with the study drug or confounds the ability to interpret data from the study
- Inability to comply with other requirements of the protocol

Informations promoteur

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT03178552?titles=b-fast&cntry=FR&rank=1