KEYNOTE-671 - (dernière mise à jour : 28/11/2019)

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Informations générales

Titre de l'étude : A Phase III, Randomized, Double-blind Trial of Platinum Doublet Chemotherapy +/-Pembrolizumab (MK-3475) as Neoadjuvant/Adjuvant Therapy for Participants With Resectable Stage IIB or IIIA Non-small Cell Lung Cancer (NSCLC)

Traitement : Néoadjuvant

Type d'étude : Hors ciblage moléculaire

Phase : II **Stade** : Localisé à Localement avancé **Ligne(s)** : 1

Schéma : Study Arms:

Experimental: NAC + Neoadjuvant/Adjuvant Pembrolizumab

Neoadjuvant: Prior to surgery, participants receive 4 cycles (cycle length: 3 weeks) of pembrolizumab [200 mg, intravenous (IV); given on cycle day 1] in combination with platinum doublet neoadjuvant chemotherapy (NAC), consisting of cisplatin [75 mg/m^2, IV; given on cycle day 1] and either Gemcitabine [1000 mg/m^2, IV; given on cycle days 1 and 8] or Pemetrexed [500 mg/m^2, IV; given on cycle day 1].

Adjuvant: 4-12 weeks following surgery, participants receive 13 cycles (cycle length: 3 weeks) of pembrolizumab [200 mg, IV; given on cycle day 1].
Interventions:
Biological: Pembrolizumab
Drug: Cisplatin
Drug: Gemcitabine
Drug: Pemetrexed
Placebo Comparator: NAC + Neoadjuvant/Adjuvant Placebo

Neoadjuvant: Prior to surgery, participants receive 4 cycles (cycle length: 3 weeks) of placebo [normal saline, IV; given on cycle day 1] in combination with platinum doublet NAC, consisting of cisplatin [75 mg/m^2, IV; given on cycle day 1] and either Gemcitabine [1000 mg/m^2, IV; given on cycle days 1 and 8] or Pemetrexed [500 mg/m^2, IV; given on cycle day 1].

Adjuvant: 4-12 weeks following surgery, participants receive 13 cycles (cycle length: 3 weeks) of placebo [normal saline, IV; given on cycle day 1].
Interventions:
Drug: Placebo
Drug: Cisplatin
Drug: Gemcitabine
Drug: Pemetrexed

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 : - Have previously untreated, histologically confirmed NSCLC and histologically confirmed Stage IIB or IIIA NSCLC.
- Be able to undergo protocol therapy, including necessary surgery.
- If male, must agree to use contraception or practice abstinence as well as refrain from donating sperm for at least 180 days after the last dose of study treatment.
- If female, may participate if not pregnant, not breastfeeding, and at least one of the following conditions apply: 1) not a woman of childbearing potential (WOCBP); or 2) a WOCBP who agrees to follow contraceptive guidance during the treatment period and for at least 180 days after the last dose of study treatment.
- Have available formalin-fixed paraffin embedded (FFPE) tumor tissue sample blocks for submission. If blocks are not available, have unstained slides for submission for central programmed death-ligand 1 (PD-L1) testing.
- Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 within 10 days of randomization.
- Have adequate organ function.

Critères de non-inclusion : - A WOCBP who has a positive urine pregnancy test within 24 hours before the first dose of study treatment.
- Has one of the following tumor locations/types:1) NSCLC involving the superior sulcus; 2) Large cell neuro-endocrine cancer (LCNEC); or 3) Sarcomatoid tumor.
-Has a history of (non-infectious) pneumonitis /interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease that requires steroids.
- Has an active infection requiring systemic therapy.
- Has had an allogenic tissue/sold organ transplant.
- Has a known severe hypersensitivity (>= Grade 3) to pembrolizumab, its active substance and/or any of its excipients.
- Has a known severe hypersensitivity (>= Grade 3) to any of the study chemotherapy agents and/or to any of their excipients.
- Has an active autoimmune disease that has required systemic treatment in past 2 years.
- Has a known history of human immunodeficiency virus (HIV) infection.
- Has a known history of Hepatitis B or Hepatitis C.
- Has a known history of active tuberculosis.
- Has a history or current evidence of any condition, therapy, or laboratory abnormality that might confound the results of the trial, interfere with the participant's participation for the full duration of the trial, or is not in the best interest of the participant to participate.
- Has known psychiatric or substance abuse disorders that would interfere with cooperating with the requirements of the trial.
- Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another co-inhibitory T-cell receptor.
- Has received prior systemic anti-cancer therapy including investigational agents for the current malignancy prior to randomization/allocation.
- Has received prior radiotherapy within 2 weeks of start of trial treatment.
- Has received a live vaccine within 30 days prior to the first dose of trial drug.
- Is currently participating in or has participated in a trial of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of trial treatment.
- Has a diagnosis of immunodeficiency or is receiving either systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior the first dose of trial drug.
- Has a known additional malignancy that is progressing or requires active treatment within the past 5 years.
- Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 180 days after the last dose of trial treatment.

Informations promoteur

Nom du promoteur : MERCK

Type de promoteur : Industriel

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Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : CHU de Rouen

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/record/NCT03425643

IFCT : https://www.ifct.fr/index.php/fr/la-recherche/item/2019-rtep7-ifct-1402