

PEARLS - MK-3475-091/ KEYNOTE-091 (dernière mise à jour : 05/08/2019)

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Informations générales

Titre de l'étude : A randomized, phase III trial with anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) versus placebo for patients with early stage NSCLC after resection and completion of standard adjuvant therapy

Traitement : Adjuvant

Type d'étude : Hors ciblage moléculaire

Phase : III **Stade** : Localisé à Localement avancé **Ligne(s)** : 2

Schéma : A Randomized, Phase 3 Trial With Anti-PD-1 Monoclonal Antibody Pembrolizumab (MK-3475) Versus Placebo for Patients With Early Stage NSCLC After Resection and Completion of Standard Adjuvant Therapy (PEARLS)

2 arms:

- Experimental: Pembrolizumab

Participants receive pembrolizumab 200 mg, intravenously (IV), every 3 weeks, for one year (expected maximum 18 doses).

- Placebo Comparator: Placebo

Participants receive placebo, IV, every 3 weeks, for one year (expected maximum 18 doses).

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 : - Pathological diagnosis of NSCLC confirmed at surgery, any histology

- Union for International Cancer Control (UICC) v7 Stage IB with T \geq 4 cm, II-IIIa NSCLC after complete surgical resection with resection margins proved microscopically free of disease (R0). Carcinoma in situ can be present at the bronchial margin

- Available tumor sample obtained at surgical resection for programmed cell death ligand-1 (PD-L1) Immunohistochemistry (IHC) expression assessment

- Eastern Cooperative Oncology Group (ECOG) Performance Status 0-1

- Adequate organ function performed within 10 days of treatment initiation

- Female participants of childbearing potential must have a negative urine or serum pregnancy test at screening (within 72 hours of first dose of study medication). If the urine test cannot be confirmed as negative, a serum pregnancy test will be required. The serum pregnancy test must be negative for the participant to be eligible

- Female participants of childbearing potential should be willing to use 2 methods of birth control or be surgically sterile, or abstain from heterosexual activity for the course of the study through 120 days after the last dose of study treatment

- Female participants who are breast feeding should discontinue nursing prior to the first dose of study medication and until 120 days after the last study treatment

- Male participants should agree to use an adequate method of contraception starting with the first dose of study treatment through 120 days after the last dose of study treatment

- Absence of severe comorbidities that in the opinion of the Investigator might hamper the participation to the study and/or the

treatment administration

- No prior or foreseen neo-adjuvant or adjuvant radiotherapy and/or neo-adjuvant chemotherapy

Critères de non-inclusion : - Evidence of disease at clinical examination and/or baseline radiological assessment as documented by contrast enhanced chest/upper abdomen CT scan, brain CT/MRI and clinical examination

- More than 4 cycles of adjuvant therapy

- Prior treatment with anti-programmed cell death (anti-PD)-1, anti-PD ligand-1/2, anti-CD137, or cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) modulators

- Live vaccine within 30 days prior to the first dose of study treatment

- Current participation or treatment with an investigational agent or use of an investigational device within 4 weeks of the first dose of study treatment

- History of Human Immunodeficiency Virus (HIV) (known HIV 1/2 antibodies positive). No known active Hepatitis B or C

- Chronic use of immunosuppressive agents and/or systemic corticosteroids or any use in the last 3 days prior to the first dose of study treatment

- History of interstitial lung disease or (non-infectious) pneumonitis that required oral or IV steroids (other than COPD exacerbation) or current pneumonitis

- Active autoimmune disease that has required systemic treatment in past 2 years

- History of a hematologic or primary solid tumor malignancy, unless in remission for at least 5 years with the exception of pT1-2 prostatic cancer Gleason score < 6, superficial bladder cancer, non melanomatous skin cancer or carcinoma in situ of the cervix

- Previous allogeneic tissue/solid organ transplant

- Active infection requiring therapy

- Surgery- or chemotherapy-related toxicity not resolved to Grade 1 with the exception of alopecia, fatigue, neuropathy and lack of appetite /nausea

- Pregnant or breastfeeding, or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 120 days after the last dose of study treatment

- Participant will not be eligible if the participant is or has an immediate family member (e.g., spouse, parent/legal guardian, sibling or child) who is investigational site or Sponsor staff directly involved with this trial, unless prospective site Review Board approval is given allowing exception to this criterion for a specific participant

Informations promoteur

Nom du promoteur : European Thoracic Oncology Platform (ETOP)

Type de promoteur : Institutionnel

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Coordonnateur : - *Mail* : - *Tél* :

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Investigateur : Radj GERVAIS

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Ouverture de l'essai : CLOS

Liens utiles

ClinicalTrials : <https://clinicaltrials.gov/ct2/show/NCT02504372?titles=pearls&cntry1=EU%3AFR&rank=6>