Protocol : PEARLS EORTC-1416-LCG

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.

This is the trial summary as assessed on clinicaltrials.gov on 18/02/2016.

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/results?term=EORTC-1416-LCG&Search=Search

Trial Design :

In this study, participants with Stage IB/II-IIIA non-small cell lung cancer (NSCLC) who have undergone surgical resection (lobectomy or pneumonectomy) with or without adjuvant chemotherapy will be treated with pembrolizumab or placebo.

The primary study hypothesis is that pembrolizumab will provide improved disease-free survival (DFS) versus placebo.

Inclusion Criteria:

Pathological diagnosis of NSCLC confirmed at surgery, any histology

UICC v7 Stage IB with T ≥ 4 cm, II-IIIA NSCLC at complete surgical resection with no residual disease (R0) after complete surgical resection (lobectomy/pneumonectomy) documented on the pathology report

Available tumor sample obtained at surgical resection for 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 must have a negative urine or serum pregnancy test at screening (within 72 hours of first dose of study medication) irrespective of their childbearing potential. 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 patients who are breast feeding should discontinue nursing prior to the first dose of study medication and until 44 months 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

Exclusion Criteria:

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 (PD)-1, anti-PD-L1/2, anti-CD137, or 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

Known history or current evidence of active tuberculosis, Hepatitis B or C, or human immunodeficiency virus (HIV)

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 pneumonitis (other than COPD exacerbation) that has required oral or IV steroids

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