ClinicalTrials.gov

Study of Pembrolizumab (MK-3475) vs Placebo for Participants With Non-small Cell Lung Cancer After Resection With or Without Standard Adjuvant Therapy (MK-3475-091/KEYNOTE-091) (PEARLS)

This study is currently recruiting participants. (see Contacts and Locations)

Verified April 2017 by Merck Sharp & Dohme Corp.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborators:
ETOP
European Organisation for Research and Treatment of Cancer - EORTC

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT02504372

First received: July 20, 2015
Last updated: April 27, 2017
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History of Changes

Purpose

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.

Condition	Intervention	Phase
Non-small Cell Lung Cancer	Biological: pembrolizumab Other: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Participant, Investigator, Outcomes Assessor
Primary Purpose: Treatment

Official Title: 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)

Resource links provided by NLM:

Genetics Home Reference related topics: lung cancer

MedlinePlus related topics: Lung Cancer

Drug Information available for: Pembrolizumab

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Disease-free Survival (DFS) [Time Frame: Up to 100 months]

Secondary Outcome Measures:

- Overall Survival (OS) [Time Frame: Up to 100 months]
- Lung Cancer Specific Survival (LCSS) [Time Frame: Up to 100 months]

Estimated Enrollment: 1380
Actual Study Start Date: November 6, 2015
Estimated Study Completion Date: August 19, 2021
Estimated Primary Completion Date: August 19, 2021 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Pembrolizumab Participants receive pembrolizumab 200 mg, intravenously (IV), every 3 weeks, for one year (expected maximum 18 doses).	Biological: pembrolizumab Other Name: MK-3475
Placebo Comparator: Placebo Participants receive placebo, IV, every 3 weeks, for one year (expected maximum 18 doses).	Other: Placebo

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Pathological diagnosis of NSCLC confirmed at surgery, any histology
- Union for International Cancer Control (UICC) v7 Stage IB with T ≥ 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

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 (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

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02504372

Contacts

Contact: Toll Free Number 1-888-577-8839

Show 19 Study Locations

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

ETOP

European Organisation for Research and Treatment of Cancer - EORTC

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT02504372 History of Changes
Other Study ID Numbers:	3475-091 2015-000575-27 (EudraCT Number) **EORTC-1416-LCG** (Other Identifier: EORTC) 163457 (Registry Identifier: JAPIC-CTI)
Study First Received:	July 20, 2015
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Keywords provided by Merck Sharp & Dohme Corp.:
NSCLC
PDL1
PD-L1
PDL

Additional relevant MeSH terms:

Lung Neoplasms	Lung Diseases
Carcinoma, Non-Small-Cell Lung	Respiratory Tract Diseases
Respiratory Tract Neoplasms	Carcinoma, Bronchogenic
Thoracic Neoplasms	Bronchial Neoplasms
Neoplasms by Site	Pembrolizumab
Neoplasms	Antineoplastic Agents

ClinicalTrials.gov processed this record on June 12, 2017