Study of Pembrolizumab (MK-3475) Versus Placebo After Complete Resection of High-Risk Stage III Melanoma (MK-3475-054/KEYNOTE-054)

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

Verified May 2016 by Merck Sharp & Dohme Corp.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
European Organisation for Research and Treatment of Cancer

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

ClinicalTrials.gov Identifier:
NCT02362594

First received: February 9, 2015
Last updated: May 20, 2016
Last verified: May 2016
History of Changes

Purpose

This study will assess whether post-resection adjuvant therapy with pembrolizumab improves recurrence-free survival (RFS) as compared to placebo for high-risk participants with melanoma (Stage IIIA [> 1 mm metastasis], IIIB and IIIC). The study will also assess whether pembrolizumab improves RFS versus placebo in the subgroup of participants with programmed cell death ligand 1 (PD-L1)-positive tumor expression. Participants will be stratified for stage of disease and region and then will be randomly assigned to receive either pembrolizumab or placebo.

Condition	Intervention	Phase
Melanoma	Biological: pembrolizumab Other: placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: Adjuvant Immunotherapy With Anti-PD-1 Monoclonal Antibody Pembrolizumab (MK- 3475) Versus Placebo After Complete Resection of High-risk Stage III Melanoma: A Randomized, Double- Blind Phase 3 Trial of the EORTC Melanoma Group

Resource links provided by NLM:

MedlinePlus related topics: Melanoma

Drug Information available for: Pembrolizumab

Genetic and Rare Diseases Information Center resources: Carcinoid Tumor Neuroepithelioma

U.S. FDA Resources

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

Primary Outcome Measures:

- Recurrence-free survival (RFS) for All Participants [Time Frame: Up to 3 years from first participant in] [Designated as safety issue: No]
- RFS for Participants with PD-L1-positive Tumor Expression [Time Frame: Up to 3 years from first participant in] [Designated as safety issue: No]

Secondary Outcome Measures:

- Distant Metastases-free Survival (DMFS) in All Participants [Time Frame: 5 years from first participant in] [Designated as safety issue: No]
- DMFS for Participants with PD-L1-positive Tumor Expression [Time Frame: 5 years from first participant in] [Designated as safety issue: No]
- Overall Survival (OS) in All Participants [Time Frame: 7 years from first participant in] [Designated as safety issue: No]
- OS in for Participants with PD-L1-positive Tumor Expression [Time Frame: 7 years from first participant in] [Designated as safety issue: No]

Estimated Enrollment: 900
Study Start Date: July 2015
Estimated Study Completion Date: January 2024
Estimated Primary Completion Date: April 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Pembrolizumab Participants receive pembrolizumab 200 mg intravenously (IV) on Day 1 of each 21-day cycle for up to 1 year	Biological: pembrolizumab
Placebo Comparator: Placebo Participants receive placebo IV on Day 1 of each 21-day cycle for up to 1 year	Other: placebo Locally sourced placebo

Eligibility

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

Criteria

Inclusion criteria:

- Completely resected Stage III melanoma
- Tumor tissue available for evaluation of PD-L1 expression
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Adequate organ function
- No prior therapy for melanoma except surgery for primary melanoma lesions (or previously treated with interferon for thick primary melanomas without evidence of lymph node involvement are eligible)
- Female participants of childbearing potential should be willing to use adequate 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 medication
- Male participants should agree to use an adequate method of birth control starting with the first dose of study therapy through 120 days after the last dose of study medication

Exclusion criteria:

- Mucosal or ocular melanoma
- History of pneumonitis requiring treatment with steroids
- History of interstitial lung disease
- History of hematologic or primary solid tumor malignancy, unless no evidence of that disease for 5 years
- Active autoimmune disease that has required systemic treatment in past 2 years
- Active infection requiring therapy
- Unstable hyperthyroidism or hypothyroidism
- Diagnosis of immunodeficiency
- Systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study medication
- Known history of human immunodeficiency virus (HIV), active Hepatitis B or C
- Treatment with live vaccine within 30 days prior to the first dose of study medication are not eligible
- Prior treatment with any anti-cytotoxic T-lymphocyte-associated protein 4 (CTLA4) monoclonal antibody or anti-PD-1, or PD-L1 or PD-L2 agent, or prior participation in any Merck pembrolizumab clinical trial
- Currently participating and receiving study therapy, or participated in a study of an investigational agent and received study therapy or used an investigation device within 4 weeks of the first dose of study medication
- 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 medication
- Patient 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 without prospective Institutional Review Board approval (by chair or designee) is given

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: NCT02362594

Contacts

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

Show 30 Study Locations

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

European Organisation for Research and Treatment of Cancer

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT02362594 History of Changes
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Study First Received:	February 9, 2015
Last Updated:	May 20, 2016
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
PD1
PDL1

Additional relevant MeSH terms:

Melanoma	Neoplasms
Neuroendocrine Tumors	Neoplasms, Nerve Tissue
Neuroectodermal Tumors	Nevi and Melanomas
Neoplasms, Germ Cell and Embryonal	Pembrolizumab
Neoplasms by Histologic Type	Antineoplastic Agents

ClinicalTrials.gov processed this record on July 05, 2016