ClinicalTrials.gov

Efficacy Study of Nivolumab Plus Ipilimumab or Nivolumab Plus Chemotherapy Against Chemotherapy in Stomach Cancer or Stomach/Esophagus Junction Cancer (CheckMate649)

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

Verified May 2017 by Bristol-Myers Squibb

Sponsor:
Bristol-Myers Squibb

Collaborator:
Ono Pharmaceutical Co. Ltd

Information provided by (Responsible Party):
Bristol-Myers Squibb

ClinicalTrials.gov Identifier:
NCT02872116

First received: August 16, 2016
Last updated: May 31, 2017
Last verified: May 2017
History of Changes

Purpose

The main purpose of this study is to compare how long patients with gastric or gastroesophageal junction cancer live after receiving nivolumab and ipilimumab or nivolumab and chemotherapy compared with patients receiving chemotherapy alone.

Condition	Intervention	Phase
Gastric Cancer Gastroesophageal Junction Cancer	Drug: Nivolumab Drug: Ipilimumab Drug: Oxaliplatin Drug: Capecitabine Drug: Leucovorin Drug: Fluorouracil	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: No masking
Primary Purpose: Treatment

Official Title: A Randomized, Multicenter, Open-Label, Phase 3 Study of Nivolumab Plus Ipilimumab or Nivolumab in Combination With Oxaliplatin Plus Fluoropyrimidine Versus Oxaliplatin Plus Fluoropyrimidine in Subjects With Previously Untreated Advanced or Metastatic Gastric or Gastroesophageal Junction Cancer

Resource links provided by NLM:

MedlinePlus related topics: Stomach Cancer

Drug Information available for: Ipilimumab Nivolumab

Genetic and Rare Diseases Information Center resources: Stomach Cancer

U.S. FDA Resources

Further study details as provided by Bristol-Myers Squibb:

Primary Outcome Measures:

- Overall survival (OS) of nivolumab + ipilimumab versus oxaliplatin + fluoropyrimidine in patients with programmed cell death ligand 1 (PD-L1) expressing tumors [Time Frame: Approximately 40 months after the first patient is randomized]

- OS of nivolumab in combination with oxaliplatin + fluoropyrimidine versus oxaliplatin + fluoropyrimidine in patients with PD-L1 expressing tumors [Time Frame: Approximately 40 months after the first patient is randomized]

Secondary Outcome Measures:

- OS of nivolumab + ipilimumab or nivolumab in combination with oxaliplatin + fluoropyrimidine versus oxaliplatin + fluoropyrimidine in all randomized patients [Time Frame: Approximately 40 months after the first patient is randomized]
- Progression-free Survival (PFS) of nivolumab + ipilimumab or nivolumab in combination with oxaliplatin + fluoropyrimidine versus oxaliplatin + fluoropyrimidine in patients with PD-L1 expressing tumors and all randomized patients [Time Frame: Approximately 40 months after the first patient is randomized]
- Time to Symptom Deterioration of nivolumab + ipilimumab or nivolumab in combination with oxaliplatin + fluoropyrimidine versus oxaliplatin + fluoropyrimidine in patients with PD-L1 expressing tumors and all randomized patients [Time Frame: Approximately 40 months after the first patient is randomized]

  Time to Symptom Deterioration assessed with Gastric Cancer Subscale questionnaire

Estimated Enrollment: 1266
Actual Study Start Date: October 4, 2016
Estimated Study Completion Date: October 11, 2020
Estimated Primary Completion Date: July 11, 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Nivolumab + Ipilimumab Nivolumab + Ipilimumab for 4 doses, followed by Nivolumab monotherapy	Drug: Nivolumab Specified dose on specified days Other Names: • Opdivo • BMS-936558 Drug: Ipilimumab Specified dose on specified days Other Names: • Yervoy • BMS-734016
Active Comparator: XELOX (Oxaliplatin + Capecitabine)	Drug: Oxaliplatin Specified dose on specified days Drug: Capecitabine Specified dose on specified days
Active Comparator: FOLFOX (Oxaliplatin + Leucovorin + Fluorouracil)	Drug: Oxaliplatin Specified dose on specified days Drug: Leucovorin Specified dose on specified days Drug: Fluorouracil Specified dose on specified days
Experimental: Nivolumab + XELOX	Drug: Nivolumab Specified dose on specified days Other Names: • Opdivo • BMS-936558 Drug: Oxaliplatin Specified dose on specified days Drug: Capecitabine Specified dose on specified days
Experimental: Nivolumab + FOLFOX	Drug: Nivolumab Specified dose on specified days Other Names: • Opdivo • BMS-936558 Drug: Oxaliplatin Specified dose on specified days Drug: Leucovorin Specified dose on specified days Drug: Fluorouracil Specified dose on specified days

Eligibility

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

Criteria

For more information regarding Bristol-Myers Squibb Clinical Trial participation, please visit www.BMSStudyConnect.com

Inclusion Criteria:

- Male or Female at least 18 years of age
- Must have gastric cancer or gastroesophageal junction cancer that cannot be operated on and that is advanced or has spread out
- Did not receive neoadjuvant or adjuvant treatment (chemotherapy, radiotherapy, or both) for their disease within the last 6 months
- Must have full activity or, if limited, must be able to walk and carry out light activities such as light house work or office work
- Must agree to provide tumor tissue sample, either from a previous surgery or biopsy within 6 months or fresh, prior to the start of treatment in this study

Exclusion Criteria:

- Presence of tumor cells in the brain or spinal cord that have not been treated
- Active known or suspected autoimmune disease
- Any serious or uncontrolled medical disorder or active infection
- Known history of positive test for human immunodeficiency virus (HIV) or known acquired immunodeficiency syndrome (AIDS)
- Any positive test result for hepatitis B or C indicating acute or chronic infection

Other protocol defined inclusion/exclusion criteria could apply

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: NCT02872116

Contacts

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please email: Clinical.Trials@bms.com

Contact: First line of the email MUST contain NCT# and Site #.

Show 161 Study Locations

Sponsors and Collaborators

Bristol-Myers Squibb

Ono Pharmaceutical Co. Ltd

Investigators

Study Director: Bristol-Myers Squibb Bristol-Myers Squibb

More Information

Additional Information:

BMS Clinical Trial Information EXIT

FDA Safety Alerts and Recalls EXIT

BMS Clinical Trial Patient Recruiting EXIT

Investigator Inquiry Form EXIT

Responsible Party: Bristol-Myers Squibb
ClinicalTrials.gov Identifier: NCT02872116 History of Changes
Other Study ID Numbers: **CA209-649**
2016-001018-76 (EudraCT Number)
Study First Received: August 16, 2016
Last Updated: May 31, 2017

Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No

Additional relevant MeSH terms:

Stomach Neoplasms	Oxaliplatin
Gastrointestinal Neoplasms	Nivolumab
Digestive System Neoplasms	Antibodies, Monoclonal
Neoplasms by Site	Antimetabolites, Antineoplastic
Neoplasms	Antimetabolites
Digestive System Diseases	Molecular Mechanisms of Pharmacological Action
Gastrointestinal Diseases	Antineoplastic Agents
Stomach Diseases	Immunosuppressive Agents
Capecitabine	Immunologic Factors
Fluorouracil	Physiological Effects of Drugs

ClinicalTrials.gov processed this record on June 05, 2017