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

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.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric Cancer</td>
<td>Drug: Nivolumab</td>
<td></td>
</tr>
<tr>
<td>Gastroesophageal Junction Cancer</td>
<td>Drug: Ipilimumab</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Oxaliplatin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Capecitabine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Leucovorin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug: Fluorouracil</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Phase 3</td>
</tr>
</tbody>
</table>

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 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 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 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)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
</table>
| Experimental: Nivolumab + Ipilimumab | Drug: Nivolumab  
Specified dose on specified days  
Other Names:  
• Opdivo  
• BMS-936555  
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-936555  
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-936555  
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

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 #.

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
FDA Safety Alerts and Recalls
BMS Clinical Trial Patient Recruiting
Investigator Inquiry Form

Responsible Party: Bristol-Myers Squibb
ClinicalTrials.gov Identifier: NCT02872116
Other Study ID Numbers: CA209-649
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
Gastrointestinal Neoplasms
Digestive System Neoplasms
Neoplasms by Site
Neoplasms
Digestive System Diseases
Gastrointestinal Diseases
Stomach Diseases
Capecitabine
Fluorouracil

Oxaliplatin
Nivolumab
Antibodies, Monoclonal
Antimetabolites, Antineoplastic
Antimetabolites
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents
Immunosuppressive Agents
Immunologic Factors
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on June 05, 2017