A Study of Nivolumab Versus Sorafenib as First-Line Treatment in Patients With Advanced Hepatocellular Carcinoma

Purpose

The purpose of this study is to determine if nivolumab or sorafenib is more effective in the treatment of Advanced Hepatocellular Carcinoma.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>LV Advanced Cancer</td>
<td>Drug: Nivolumab</td>
<td>Phase 3</td>
</tr>
<tr>
<td></td>
<td>Drug: Sorafenib</td>
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</tbody>
</table>

Study Type: Interventional  
Study Design: Allocation: Randomized  
Endpoint Classification: Efficacy Study  
Intervention Model: Parallel Assignment  
Masking: Open Label  
Primary Purpose: Treatment  

Official Title: A Randomized, Multi-center Phase III Study of Nivolumab Versus Sorafenib as First-Line Treatment in Patients With Advanced Hepatocellular Carcinoma (CheckMate 459: CHECKpoint Pathway and nivoluMAb Clinical Trial Evaluation 459)  

Resource links provided by NLM:  
Drug Information available for: Sorafenib, Sorafenib tosylate, Nivolumab  
Genetic and Rare Diseases Information Center resources: Liver Cancer  
U.S. FDA Resources  

Further study details as provided by Bristol-Myers Squibb:  

Primary Outcome Measures:  
- Time To Progression (TTP) [ Time Frame: Approximately 18 months ] [ Designated as safety issue: No ]  
  It is defined as the time from the date of randomization to the date of the first objectively documented tumor progression.  
- Overall Survival (OS) [ Time Frame: Approximately 33 months ] [ Designated as safety issue: No ]  
  It is defined as the time from the date of randomization to the date of death due to any cause.

Secondary Outcome Measures:  
- Overall Response Rate (ORR) [ Time Frame: Approximately 33 months ] [ Designated as safety issue: No ]  
  It is defined as the proportion of all randomized subjects whose best overall response (BOR) is either a Complete response (CR) or Partial...
response (PR).

- Progression-Free Survival (PFS) [ Time Frame: Approximately 33 months ] [ Designated as safety issue: No ]
  It is defined as the time from the date of randomization to the date of the first objectively documented tumor progression as assessed by blinded independent central review (BICR) according to RECIST 1.1 or death due to any cause.

- Programmed death (PD)-L1 expression [ Time Frame: Approximately 33 months ] [ Designated as safety issue: No ]

Estimated Enrollment: 726
Study Start Date: November 2015
Estimated Study Completion Date: June 2019
Estimated Primary Completion Date: May 2017 (Final data collection date for primary outcome measure)

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<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</thead>
<tbody>
<tr>
<td>Experimental: Nivolumab</td>
<td>Drug: Nivolumab</td>
</tr>
<tr>
<td>Nivolumab specified dose on specified days</td>
<td></td>
</tr>
<tr>
<td>Active Comparator: Sorafenib</td>
<td>Drug: Sorafenib</td>
</tr>
<tr>
<td>Sorafenib specified dose on specified days</td>
<td></td>
</tr>
</tbody>
</table>

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

For more information regarding BMS clinical trial participation, please visit www.BMSStudyConnect.com

Inclusion Criteria:
- Histologically confirmed advanced hepatocellular carcinoma, not eligible for surgical and/or locoregional therapies; or progressive disease after surgical and/or locoregional therapies
- Locoregional therapy for hepatocellular carcinoma (HCC) must be completed at least 4 weeks prior to the baseline scan
- Child-Pugh Class A
- Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1

Exclusion Criteria:
- Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC
- Prior liver transplant
- Active, known, or suspected autoimmune disease

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: NCT02576509

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 94 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
BMS clinical trial educational resource
Investigator Inquiry form
FDA Safety Alerts and Recalls

No publications provided

Responsible Party: Bristol-Myers Squibb
ClinicalTrials.gov Identifier: NCT02576509
Other Study ID Numbers: CA209-459
Study First Received: October 13, 2015
Last Updated: January 26, 2016

Health Authority:
- United States: Food and Drug Administration
- United States: Institutional Review Board
- Australia: Department of Health and Ageing Therapeutic Goods Administration
- Austria: Agency for Health and Food Safety
- Belgium: Ethics Committee
- Belgium: Federal Agency for Medicinal Products and Health Products
- Belgium: Federal Agency for Medicines and Health Products, FAMHP
- Belgium: Institutional Review Board
- Canada: Ethics Review Committee
- Canada: Health Canada
- Canada: Institutional Review Board
- Canada: Public Health Agency of Canada
- Czech Republic: Ethics Committee
- Czech Republic: State institute for Drug Control
- France: Agence Nationale de Sécurité du Medicament et des produits de santé
- France: Committee for the Protection of Personnes
- France: Haute Autorité de Santé Transparency Commission
- France: Institutional Ethical Committee
- France: National Consultative Ethics Committee for Health and Life Sciences
- Germany: Paul-Ehrlich-Institut
- Hong Kong: Department of Health
- Hong Kong: Ethics Committee
- Israel: Ministry of Health
- Italy: The Italian Medicines Agency
- Japan: Pharmaceuticals and Medical Devices Agency
- Korea: Ministry of Food and Drug Safety
- Poland: Ethics Committee
- Poland: Ministry of Health
- Singapore: Domain Specific Review Boards
- Singapore: Health Sciences Authority
- Singapore: Institutional Review Board
- Spain: Ethics Committee
- Spain: Spanish Agency of Medicines
- Sweden: Medical Products Agency
- Sweden: Regional Ethical Review Board
- Switzerland: Swissmedic
- Taiwan: Food and Drug Administration
- Taiwan: Center for Drug Evaluation
- United Kingdom: Department of Health
- United Kingdom: Food Standards Agency
- United Kingdom: Medicines and Healthcare Products Regulatory Agency
- United Kingdom: National Institute for Health Research
- United Kingdom: Research Ethics Committee
- Russia: Ethics Committee
- Russia: Ministry of Health

Additional relevant MeSH terms:
- Carcinoma, Hepatocellular
- Adenocarcinoma
- Carcinoma
- Digestive System Diseases
- Digestive System Neoplasms
- Liver Diseases
- Liver Neoplasms
- Neoplasms by Site
- Neoplasms, Glandular and Epithelial
- Sorafenib
- Antineoplastic Agents
- Enzyme Inhibitors
- Molecular Mechanisms of Pharmacological Action
- Pharmacologic Actions
<table>
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<tr>
<th>Neoplasms</th>
<th>Protein Kinase Inhibitors</th>
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<tr>
<td>Neoplasms by Histologic Type</td>
<td>Therapeutic Uses</td>
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</table>

ClinicalTrials.gov processed this record on February 07, 2016