A Study of Nivolumab Plus Brentuximab Vedotin in Patients Between 5 and 30 Years Old, With Hodgkin’s Lymphoma (cHL), Relapsed or Refractory From First Line Treatment (CheckMate 744)

ClinicalTrials.gov Identifier: NCT02927769

Recruitment Status: Recruiting
First Posted: October 7, 2016
Last Update Posted: March 27, 2018

See Contacts and Locations

Sponsor:
Bristol-Myers Squibb

Collaborator:
Seattle Genetics, Inc.

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

Study Description

Brief Summary:
The purpose of this study is to determine whether nivolumab plus brentuximab vedotin (followed by brentuximab vedotin plus bendamustine in patient with suboptimal response) is safe and effective in treating patients with Hodgkin’s lymphoma (cHL). Eligible patients are children, adolescents, and young adults relapsed or refractory to first line.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hodgkin Disease</td>
<td>Biological: Nivolumab</td>
<td>Phase 2</td>
</tr>
<tr>
<td></td>
<td>Biological: brentuximab vedotin</td>
<td></td>
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<tr>
<td></td>
<td>Biological: bendamustine</td>
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</tbody>
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Study Design
**Study Type**: Interventional (Clinical Trial)  
**Estimated Enrollment**: 80 participants  
**Allocation**: Non-Randomized  
**Intervention Model**: Parallel Assignment  
**Masking**: None (Open Label)  
**Primary Purpose**: Treatment  
**Official Title**: Risk-based, Response-adapted, Phase II Open-label Trial of Nivolumab + Brentuximab Vedotin (N + Bv) for Children, Adolescents, and Young Adults With Relapsed/Refractory (R/R) CD30 + Classic Hodgkin Lymphoma (cHL) After Failure of First-line Therapy, Followed by Brentuximab + Bendamustine (Bv + B) for Participants With a Suboptimal Response (CheckMate 744: CHECKpoint Pathway and Nivolumab Clinical Trial Evaluation)  
**Actual Study Start Date**: March 27, 2017  
**Estimated Primary Completion Date**: March 28, 2021  
**Estimated Study Completion Date**: March 27, 2022

**Resource links provided by the National Library of Medicine**  
MedlinePlus related topics:  
- Hodgkin Disease  
- Lymphoma  
Drug Information available for:  
- Bendamustine hydrochloride  
- Bendamustine  
- Brentuximab vedotin  
- Nivolumab  
Genetic and Rare Diseases Information Center resources:  
- Lymphosarcoma  
- Hodgkin Lymphoma  
U.S. FDA Resources

### Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
</table>
| Experimental: Nivolumab + brentuximab vedotin | Biological: Nivolumab  
Specified Dose on Specified Days  
Other Names:  
- BMS-936558  
- Opdivo  
Biological: brentuximab vedotin  
Specified Dose on Specified Days |
| Experimental: brentuximab vedotin + bendamustine | Biological: brentuximab vedotin  
Specified Dose on Specified Days  
Biological: bendamustine  
Specified Dose on Specified Days |

### Outcome Measures

**Primary Outcome Measures**
Event Free Survival (EFS) [Time Frame: Up to 5 years]
Low Risk Group. Based on blinded independent central review (BICR)

Complete Metabolic Response (CMR) rate [Time Frame: Up to 5 years]
Standard Risk Group. This is the rate prior to high-dose chemotherapy followed by autologous stem cell transplant (HDCT/ASCT) based on the blinded independent central review (BICR).

Complete Metabolic Response (CMR) rate at any time prior to radiation therapy [Time Frame: Up to 5 years]
Low Risk Group. The CMR rate is defined as the proportion of all response-evaluable participants who, assessed by the BICR, achieve best response of CMR using Lugano 2014 criteria.

Secondary Outcome Measures:

1. Overall Response Rate (ORR) [Time Frame: Up to 12 weeks]
   Based on blinded independent central review (BICR)

2. Progression Free Survival Rate (PFSR) [Time Frame: Up to 5 years]
   Based on the blinded independent central review (BICR)

3. Duration of Response (DOR) [Time Frame: Up to 5 years]
   Based on the blinded independent central review (BICR)

4. Incidence of serious and non-serious adverse events of nivolumab (BMS-936558) and brentuximab when given in combination. [Time Frame: Up to 5 years]
   measured by number of patients

5. Incidence of clinically significant abnormalities in general laboratory tests of nivolumab (BMS-936558) and brentuximab when given in combination. [Time Frame: Up to 5 years]
   Hematology, Chemistry and Urinalysis

6. Incidence of clinically significant vital sign measurements of nivolumab (BMS-936558) and brentuximab when given in combination. [Time Frame: Up to 5 years]
   Temperature, Blood Pressure and Heart Rate

Eligibility Criteria
Information from the National Library of Medicine

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, Learn About Clinical Studies.

Ages Eligible for Study:  5 Years to 30 Years   (Child, Adult)
Sexes Eligible for Study:  All
Accepts Healthy Volunteers:  No

Criteria

Inclusion Criteria:

- Classic Hodgkin Lymphoma (cHL), relapsed or refractory
- Minimal limitation on activities of daily living as measured by Karnofsky ≥ 50 for participants > 16 years of age or Lansky ≥ 50 for participants ≤ 16 years of age.
- One prior anti-cancer therapy that did not work

Exclusion Criteria:

- Active, known, or suspected autoimmune disease or infection
- Active cerebral/meningeal disease related to the underlying malignancy
- More than one line of anti-cancer therapy or no treatment at all
- Received a stem cell transplant for Hodgkin Lymphoma and/or a solid organ transplant
- Prior treatment with any drug that targets T cell co-stimulation pathways (such as checkpoint inhibitors)

Other protocol defined inclusion/exclusion criteria could apply

Contacts and Locations

Contacts and Locations

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT02927769

Information from the National Library of Medicine

Contacts

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please contact the sponsor.

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

Show 101 Study Locations

Sponsors and Collaborators

Bristol-Myers Squibb
Seattle Genetics, Inc.

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: NCT02927769  History of Changes
Other Study ID Numbers: CA209-744
2016-002347-41 (EudraCT Number)

First Posted: October 7, 2016  Key Record Dates
Last Update Posted: March 27, 2018
Last Verified: March 2018

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

Additional relevant MeSH terms:
Hodgkin Disease  Bendamustine Hydrochloride
Lymphoma  Antibodies, Monoclonal
Neoplasms by Histologic Type  Antineoplastic Agents
Neoplasms  Immunologic Factors
Lymphoproliferative Disorders  Physiological Effects of Drugs
Lymphatic Diseases  Antineoplastic Agents, Alkylating
Immunoproliferative Disorders  Alkylating Agents
Immune System Diseases  Molecular Mechanisms of Pharmacological Action
Nivolumab