# 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

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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.

| Condition or disease | Intervention/treatment | Phase |
|---|---|---|
| Hodgkin Disease | Biological: Nivolumab<br>Biological: brentuximab vedotin<br>Biological: bendamustine | Phase 2 |

## Study Design

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| | |
|---|---|
| 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

Go to

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

## Outcome Measures

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Primary Outcome Measures :

1. Event Free Survival (EFS) [ Time Frame: Up to 5 years ]

   Low Risk Group. Based on blinded independent central review (BICR)

2. 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).

3. 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** Go to

**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**

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

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

Go to

**Information from the National Library of Medicine**

*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***

**Contacts**

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no contact informatior

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

Go to

**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 |

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|---|---|
| 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 | |