Trial record **1 of 1** for: Brentuximab C25002
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Study of Brentuximab Vedotin (SGN-35) in Pediatric Patients With Relapsed or Refractory Systemic Anaplastic Large-Cell Lymphoma or Hodgkin Lymphoma

This study is ongoing, but not recruiting participants.

Sponsor:
Millennium Pharmaceuticals, Inc.

Information provided by (Responsible Party):
Millennium Pharmaceuticals, Inc.

ClinicalTrials.gov Identifier:
NCT01492088

First received: December 12, 2011
Last updated: August 17, 2016
Last verified: August 2016
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

This is a phase 1/2, open-label, single-agent, multi-center, dose-escalation study of **brentuximab** vedotin in pediatric patients with relapsed or refractory systemic anaplastic large-cell lymphoma or Hodgkin lymphoma

Condition	Intervention	Phase
Hodgkin Lymphoma Anaplastic Large-cell Lymphoma	Drug: **brentuximab** vedotin	Phase 1 Phase 2

Study Type: Interventional
Study Design: Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase 1/2 Study of **Brentuximab** Vedotin in Pediatric Patients With Relapsed or Refractory Systemic Anaplastic Large-Cell Lymphoma or Hodgkin Lymphoma

Resource links provided by NLM:

MedlinePlus related topics: Hodgkin Disease Lymphoma

Drug Information available for: Brentuximab vedotin

Genetic and Rare Diseases Information Center resources: Lymphosarcoma Hodgkin Lymphoma Lymphoma, Large-cell Anaplastic Large Cell Lymphoma

U.S. FDA Resources

Further study details as provided by Millennium Pharmaceuticals, Inc.:

Primary Outcome Measures:

- Number of Adverse events, serious adverse events, assessments of clinical and laboratory values, and vital sign measurements (phase 1) [Time Frame: From the time informed consent is signed through 30 days after the last dose of study drug, approximately 12 months] [Designated as safety issue: Yes]

  To assess the safety profile and determine the pediatric maximum tolerated dose and/or recommended phase 2 dose of brentuximab vedotin

- Plasma concentrations of **brentuximab** vedotin, total therapeutic antibody, and monomethyl auristatin E (MMAE) (phase 1) [Time Frame: All (21 day) Cycles: Day 1; Cycle 1: Days 2, 3, 5, 14; Cycle 2: Days 2 (phase 1 only), 3, 5; Cycle 8: Days 2, 3, 5, 14] [Designated as safety issue: No]

  Pharmacokinetics of brentuximab vedotin

- Overall response rate (CR, PR) as determined by an IRF using PET, CT, MRI and, clinical assessment according to IWG revised response criteria (phase 2) [Time Frame: PET: At Screening, Cycles 2 and 7. No additional scans needed after Cycle 7 unless clinically indicated. CT

scans and MRI: Screening, Cycle 2, 4, 7, 10, 13, 16 and end of treatment and every 12 weeks thereafter for 12 months]
[Designated as safety issue: No]

Complete response + partial response

Secondary Outcome Measures:

- Anti-therapeutic antibody (ATA) titer and neutralizing ATA titer (phase 1 & phase 2) [Time Frame: At screening, predose Day 1 at Cycle 2 and Cycle 4, and at end of treatment] [Designated as safety issue: No]

  Immunogenicity of brentuximab vedotin

- Overall response rate (CR, PR) as determined by an IRF using PET, CT, MRI and, clinical assessment according to IWG revised response criteria (phase 1) [Time Frame: PET: At Screening, Cycles 2 and 7. No additional scans needed after Cycle 7 unless clinically indicated. CT scans and MRI: Screening, Cycle 2, 4, 7, 10, 13, 16 and end of treatment and every 12 weeks therafter for 12 months]
  [Designated as safety issue: No]

  Complete response + partial response

- Time to progression (phase 1 & phase 2) [Time Frame: From the first dose of study treatment to the date of first documented progressive disease] [Designated as safety issue: No]
- Time to response (phase 1 & phase 2) [Time Frame: From the first dose of study treatment to the date of first documentation of a complete or partial response] [Designated as safety issue: No]
- Duration of response (phase 1 & phase 2) [Time Frame: From the date of first documentation of a response to the date of progressive disease] [Designated as safety issue: No]
- Event-free survival (phase 1 & phase 2) [Time Frame: From first dose until treatment failure] [Designated as safety issue: No]
- Progression-free survival (phase 1 & phase 2) [Time Frame: From the first dose of study treatment to disease progression or death]
  [Designated as safety issue: No]
- Overall survival (phase1 and phase 2) [Time Frame: From the first dose of study treatment to date of death] [Designated as safety issue: No]
- Number of Adverse events, serious adverse events, assessments of clinical and laboratory values, and vital sign measurements (phase 2)
  [Time Frame: From the time informed consent is signed through 30 days after the last dose of study drug] [Designated as safety issue: Yes]
- Plasma concentrations of **brentuximab** vedotin, total therapeutic antibody, and monomethyl auristatin E (MMAE) (phase 2) [Time Frame: All Cycles: Day 1; Cycle 1: Days 2, 3, 5, 14; Cycle 2: Days 3, 5; Cycle 8: Days 2, 3, 5, 14] [Designated as safety issue: No]

  Pharmacokinetics of brentuximab vedotin

Enrollment:	30
Study Start Date:	April 2012
Estimated Study Completion Date:	October 2016
Estimated Primary Completion Date:	October 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Arm 1 **brentuximab** vedotin	Drug: **brentuximab** vedotin **Brentuximab** vedotin will be administered by intravenous (IV) infusion once every 21 days. Each 21-day treatment cycle is composed of 1 day study drug treatment, followed by a monitoring period of 20 days. Patients may receive **brentuximab** vedotin for up to 16 cycles. Treatment with **brentuximab** vedotin beyond 16 cycles may be allowed for responding patients after discussion between the investigator and medical monitor. Following the final dose of **brentuximab** vedotin patients will be monitored for safety for a minimum of 30 days. Patients will be followed for progression-free survival (PFS) and overall survival (OS) every 12 weeks for 12 months after the end of treatment (EOT) visit. Thereafter, assessment for OS will continue every 6 months until the sooner of death or study closure or a maximum of 2 years after enrollment of the last patient. Other Names: • SGN-35 • ADCETRIS

Eligibility

Ages Eligible for Study:	2 Years to 18 Years (Child, Adult)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Male or female patients aged 2 to <18 years (5 to <18 years for Hodgkin lymphoma (HL))

- Diagnosis of systemic anaplastic large-cell lymphoma, or Hodgkin lymphoma for which standard, curative, life-prolonging, or palliative treatment does not exist or is no longer effective
- Patients with systemic anaplastic large-cell lymphoma (sALCL) must have documented anaplastic lymphoma kinase (ALK) status and must be beyond first remission or refractory to front-line chemotherapy
- Patients diagnosed with any relapsed or refractory CD30+ hematologic malignancy (e.g., primary mediastinal B-cell lymphoma) may be included in phase 1 of the study
- Patients with HL must be in their second of later relapse, have failed systemic chemotherapy either as induction therapy for advanced stage disease or salvage therapy, and were ineligible for, refused, or previously received a stem cell transplant
- Performance score ≥ 60 from Lansky Play Performance Scale if < 16 years
- Negative pregnancy test
- Fertile patients must use 2 effective methods of contraception prior to and through 6 months after the last dose of the study drug

Exclusion Criteria:

- Current diagnosis of primary cutaneous ALCL (those with systemic ALCL are eligible)
- Received an allogeneic stem cell transplant <3 months prior to the first dose of study medication, or presence of polymerase chain reaction (PCR)-detectable cytomegalovirus (CMV) in any post-allogeneic transplant patient
- Receiving immunosuppressive therapy
- Receiving systemic therapy for chronic graft-versus-host disease (topical therapy is allowed)
- Previous treatment with any anti-CD30 antibody
- Therapeutic monoclonal antibody use within the longer of 6 weeks or 5 plasma half-lives
- Systemic cardiac disease that would, in the opinion of the investigator or medical monitor, interfere with assessment of efficacy or safety of the drug
- History of another primary malignancy not in remission for at least 3 years (the following are exempt from the 3-year limit: nonmelanoma skin cancer and cervical carcinoma in situ on biopsy or a squamous intraepithelial lesion on Pap smear)
- Known active cerebral/meningeal disease, including signs or symptoms of progressive multifocal leukoencephalopathy (PML) or any history of PML
- History of cirrhosis
- Active systemic viral, bacterial, or fungal infection requiring antimicrobial, antiviral therapy or antifungal therapy within 2 weeks prior to the first dose of study drug (routine antimicrobial prophylaxis is acceptable)
- Concurrent therapy with other anti-neoplastic or experimental agents
- Systemic corticosteroid therapy <7 days prior to first dose of the study medication
- Any serious underlying medical condition that, in the opinion of the investigator or medical monitor, would impair their ability to receive or tolerate the planned treatment
- Known hypersensitivity to recombinant proteins, murine proteins, or any excipient contained in the drug formulation
- Received nitrogen mustard agents, melphalan, or BCNU therapy within 6 weeks prior to the first study dose
- Prior autologous hematopoietic stem cell infusion <4 weeks prior to first study dose
- Grade 2 or greater unresolved toxicity from prior antineoplastic therapy
- Grade 2 or greater peripheral neuropathy
- Female patients who are both lactating and breastfeeding, or have a positive serum pregnancy test during the screening period or a positive urine pregnancy test on Day 1 before the first dose of study drug
- Received local palliative radiation therapy <14 days prior to the first dose of study medication
- Received radiation therapy to more than 25% of the bone marrow-containing spaces < 84 days prior to first dose of study medication
- Received a strong or listed moderate inhibitor of CYP3A4 <2 weeks prior to first study dose
- Patients must have fully recovered from the acute toxic effects of all prior chemotherapy, immunotherapy, or radiotherapy prior to entering this study

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: NCT01492088

Locations

United States, Colorado
Aurora, Colorado, United States

United States, Missouri
Kansas City, Missouri, United States

United States, New York
New York, New York, United States

United States, Texas
Houston, Texas, United States

France
Bordeaux Cedex, France
Lyon, France
Paris Cedex 12, France

Germany
Berlin, Germany
Frankfurt, Germany
Giessen, Germany
Halle, Germany
Munster, Germany

Italy
Padova, Italy
Roma, Italy

Mexico
Mexico Df, Mexico

Netherlands
Rotterdam, Netherlands

Spain
Barcelona, Spain

United Kingdom
London, United Kingdom

Sponsors and Collaborators

Millennium Pharmaceuticals, Inc.

Investigators

Study Director: Medical Monitor Millennium Pharmaceuticals, Inc.

More Information

Responsible Party:	Millennium Pharmaceuticals, Inc.
ClinicalTrials.gov Identifier:	NCT01492088 History of Changes
Other Study ID Numbers:	**C25002** 2011-001240-29 U1111-1158-2613 133300410A0384 NL38209.078.11
Study First Received:	December 12, 2011
Last Updated:	August 17, 2016
Health Authority:	United States: Food and Drug Administration

Keywords provided by Millennium Pharmaceuticals, Inc.:

Pediatric	Anaplastic Large-cell
Lymphoma	Relapsed
Hodgkin	Refractory

Additional relevant MeSH terms:

Lymphoma	Lymphatic Diseases
Lymphoma, Non-Hodgkin	Immunoproliferative Disorders
Hodgkin Disease	Immune System Diseases
Lymphoma, Large-Cell, Anaplastic	Lymphoma, T-Cell
Neoplasms by Histologic Type	Antibodies, Monoclonal
Neoplasms	Immunologic Factors
Lymphoproliferative Disorders	Physiological Effects of Drugs

ClinicalTrials.gov processed this record on November 04, 2016