Expanded Access Protocol of Blinatumomab in Pediatric and Adolescent Subjects With Relapsed and/or Refractory B-precursor Acute Lymphoblastic Leukemia (ALL) (RIALTO)

Expanded access is currently available for this treatment.

Verified November 2016 by Amgen

Sponsor:
Amgen

Information provided by (Responsible Party):
Amgen

ClinicalTrials.gov Identifier:
NCT02187354

First received: July 9, 2014
Last updated: November 11, 2016
Last verified: November 2016
History of Changes

Purpose

Primary Objective:

To estimate the incidence of treatment-emergent and treatment-related adverse events during treatment with **blinatumomab** in pediatric and adolescent subjects with B-precursor ALL in second or later bone marrow relapse, in any marrow relapse after alloHSCT, or refractory to other treatments

Secondary Objective(s):

To describe key efficacy outcomes, including incidence of complete response (CR) within 2 cycles of **blinatumomab**, minimal residual disease (MRD) remission within 2 cycles of **blinatumomab**, relapse free survival (RFS), overall survival (OS), incidence of alloHSCT, and 100-day mortality after alloHSCT.

Hypotheses:

A formal statistical hypothesis will not be tested. The incidence of treatment-emergent and treatment-related adverse events will be estimated.

Study Endpoints:

- Incidence of treatment-emergent and treatment-related adverse events
- Incidence of CR within 2 cycles of **blinatumomab**
- MRD remission within 2 cycles of **blinatumomab**
- RFS
- OS
- Incidence of alloHSCT
- 100-day mortality after alloHSCT

Study Design:

Multi-center, open-label, single-arm expanded access protocol

Condition	Intervention	Phase
Relapsed/Refractory B-Precursor Acute Lymphoblastic Leukemia (ALL)	Drug: **Blinatumomab**	Phase 4

Study Type: Expanded Access What is Expanded Access?

Official Title: An Open-Label, Multi-center, Expanded Access Protocol of **Blinatumomab** for the Treatment of Pediatric and Adolescent Subjects With Relapsed and/or Refractory B-precursor Acute Lymphoblastic Leukemia (ALL)

Resource links provided by NLM:

MedlinePlus related topics: Chronic Lymphocytic Leukemia Leukemia

Drug Information available for: Blinatumomab

Genetic and Rare Diseases Information Center resources: Acute Lymphoblastic Leukemia Lymphosarcoma

U.S. FDA Resources

Further study details as provided by Amgen:

Intervention Details:

Drug: **Blinatumomab**

A single cycle of **blinatumomab** treatment is 6 weeks in duration, which includes 4 weeks of **blinatumomab** CIVI followed by a 2 week treatment-free interval. In the first cycle, if the patient shows an M3 bone marrow, the initial dose of **blinatumomab** will be 5µg/m2/day for the first 7 days which will be escalated to 15µg/m2/day on D8 through D29. For all subsequent cycles 15µg/m2/day will be the dose for all 4 weeks of continuous treatment. In case of M2 bone marrow at screening, the initial dose will start at 15µg/m2/day for the first 7 days of treatment and no dose step will be performed at D8. For all subsequent cycles the dose will stay 15µg/m2/day. A dose of 9µg/day for the initial dose (if applicable for an M3 bone marrow at screening) and 28µg/day for the escalated dose after dose step should not be exceeded regardless of body surface area, cytomorphology, or immunophenotype. The dose for the next cycle has to be recalculated in case a weight change of ≥ 10% occurs within a cycle.

Eligibility

Ages Eligible for Study: up to 17 Years (Child)
Genders Eligible for Study: Both

Criteria

This study seeks pediatric subjects aged > 28 days and < 18 years with relapsed/refractory B-precursor ALL, to include:

- Second or later bone marrow relapse,
- Any marrow relapse after alloHSCT, or
- Refractory to prior treatments:
  - For patients in first relapse: failure to achieve a CR following full standard reinduction chemotherapy regimen
  - For patients who have not achieved a first remission: failure to achieve remission following a full standard induction regimen
- Subjects previously treated with blinatumomab may be eligible, if blinatumomab was tolerated and response was achieved Note: Selection of sites for this expanded access protocol is limited to sites that have gained experience in the use of blinatumomab in the previous Ph1/2 Pediatric and Adolescent trial MT103-205. If other institutions have patients they would like to put on the expanded access protocol, these patients need to be referred to the open participating sites.

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: NCT02187354

Contacts

Contact: Amgen Call Center 866-572-6436

Locations

United States, Colorado

Research Site
Aurora, Colorado, United States, 80045

United States, Ohio

Research Site
Cincinnati, Ohio, United States, 45229

United States, Tennessee

Research Site
Memphis, Tennessee, United States, 38105

United States, Utah

Research Site
Salt Lake City, Utah, United States, 84113

Austria

Research Site
Wien, Austria, 1090

France

Research Site
Marseille cedex 5, France, 13385

Research Site
Paris, France, 75019

Germany

Research Site
Berlin, Germany, 13353

Research Site
Frankfurt am Main, Germany, 60590

Research Site
Kiel, Germany, 24105

Research Site
München, Germany, 80337

Research Site
Münster, Germany, 48149

Research Site
Tübingen, Germany, 72076

Research Site
Würzburg, Germany, 97080

Italy

Research Site
Monza (MB), Italy, 20900

Research Site
Roma, Italy, 00165

Switzerland

Research Site
Zuerich, Switzerland, 8032

United Kingdom

Research Site
Sheffield, United Kingdom, S10 2TH

Sponsors and Collaborators

Amgen

Investigators

Study Director: MD Amgen

More Information

Additional Information:

AmgenTrials clinical trials website EXIT

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ClinicalTrials.gov Identifier:	NCT02187354 History of Changes
Other Study ID Numbers:	20130320
Study First Received:	July 9, 2014
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Additional relevant MeSH terms:

Blinatumomab
Leukemia
Precursor Cell Lymphoblastic Leukemia-Lymphoma
Leukemia, Lymphoid
Neoplasms by Histologic Type
Lymphatic Diseases
Immunoproliferative Disorders
Immune System Diseases
Antibodies, Bispecific
Antineoplastic Agents

Neoplasms
Lymphoproliferative Disorders

Immunologic Factors
Physiological Effects of Drugs

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