### 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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relapsed/Refractory B-Precursor Acute Lymphoblastic Leukemia (ALL)</td>
<td>Drug: Blinatumomab</td>
<td>Phase 4</td>
</tr>
</tbody>
</table>

**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)

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**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
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
  - Paris, France, 75019

### Germany
- **Research Site**
  - Berlin, Germany, 13353
  - Frankfurt am Main, Germany, 60590
  - Kiel, Germany, 24105
  - München, Germany, 80337
  - Münster, Germany, 48149
  - Tübingen, Germany, 72076
  - Würzburg, Germany, 97080

### Italy
- **Research Site**
  - Monza (MB), Italy, 20900
  - 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** [Link](https://clinicaltrials.gov/ct2/show/NCT02187354?term=Blinatumomab+Rialto&rank=1)

- **Responsible Party:** Amgen
- **ClinicalTrials.gov Identifier:** [NCT02187354](https://clinicaltrials.gov/ct2/show/NCT02187354) [History of Changes](#)
- **Other Study ID Numbers:** 20130320
- **Study First Received:** July 9, 2014
- **Last Updated:** November 11, 2016
- **Health Authority:**
  - United Kingdom: Medicines and Healthcare Products Regulatory Agency
  - Switzerland: Swissmedic
  - United States: Food and Drug Administration
  - Germany: Paul-Ehrlich-Institut
  - Italy: National Institute of Health
  - Austria: Agency for Health and Food Safety
  - France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

**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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