Clinical Study Results

1. Study Name

Title of the Study:	Long-term Follow-up of Adult Philadelphia Chromosome-negative Acute Lymphoblastic Leukemia Relapsed Refractory Patients Enrolled in Study 00103311
Protocol Number:	20180138
Date of This Summary:	17 November 2021

What does this summary cover?

This summary shows the main results from one clinical study. The results are only for this study. Other studies may find different results. Researchers and health authorities look at the results of many studies to decide which medicines work best and are safest for participants.

Amgen has committed to make research results available to the public. This summary has been provided as part of that commitment and should not be used for any other purpose. It should not be considered to make a claim for any product or to guide treatment decisions.

Some information in this summary may be different from the approved labelling for blinatumomab. Your healthcare professional should refer to the full prescribing information for proper use of blinatumomab.

2. Who Sponsored This Study?

Amgen Inc.
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Amgen Inc. is the sponsor of the study and makes blinatumomab, the medicine tested in the study. Amgen would like to thank everyone who participated in this study and feels it is important to share the results of this study.

3. General Information About the Clinical Trial

Where and when was the study done?

- This study took place in 18 countries.
- The study began in December 2019 and ended in September 2020.
- The study was completed as planned.

Why was the study done?

Blinatumomab is an immunotherapy medicine that is used to treat people with acute lymphoblastic leukemia (ALL), a type of cancer of the white blood cells. Blinatumomab helps the immune system to find and destroy cancer cells.

This study included people with acute lymphoblastic leukemia who had participated in a previous study called the TOWER study (00103311). The Philadelphia chromosome is an abnormal chromosome that is sometimes found in the leukemia cells. Participants in the TOWER study did not have the Philadelphia chromosome. Additionally, participants in the TOWER study had ALL that either did not improve with treatment, or that had returned after initially improving with treatment. Participants received either standard chemotherapy treatment or blinatumomab during the TOWER study.

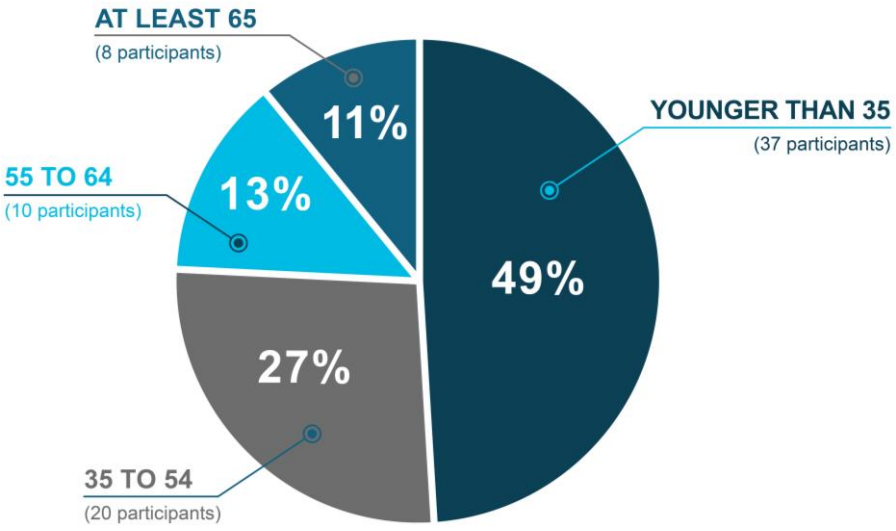
This was a phase 4 study, which is an additional study done after a medicine has been approved by a government health authority for doctors to prescribe to patients. TOWER study was closed early because the main purpose of the study was met, so this study was done as part of the process required for continuous approval of

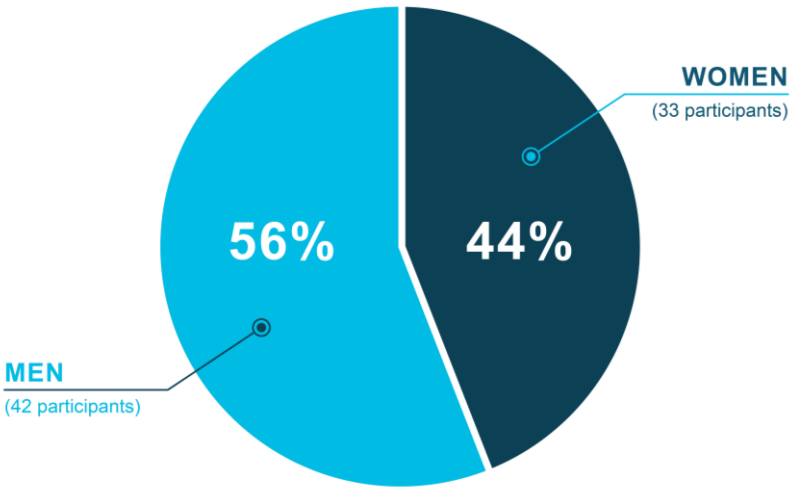
medicines in the European Union. The purpose of the study was to learn whether participants were still alive after completing the TOWER study.

4. Who Was Included in This Study?

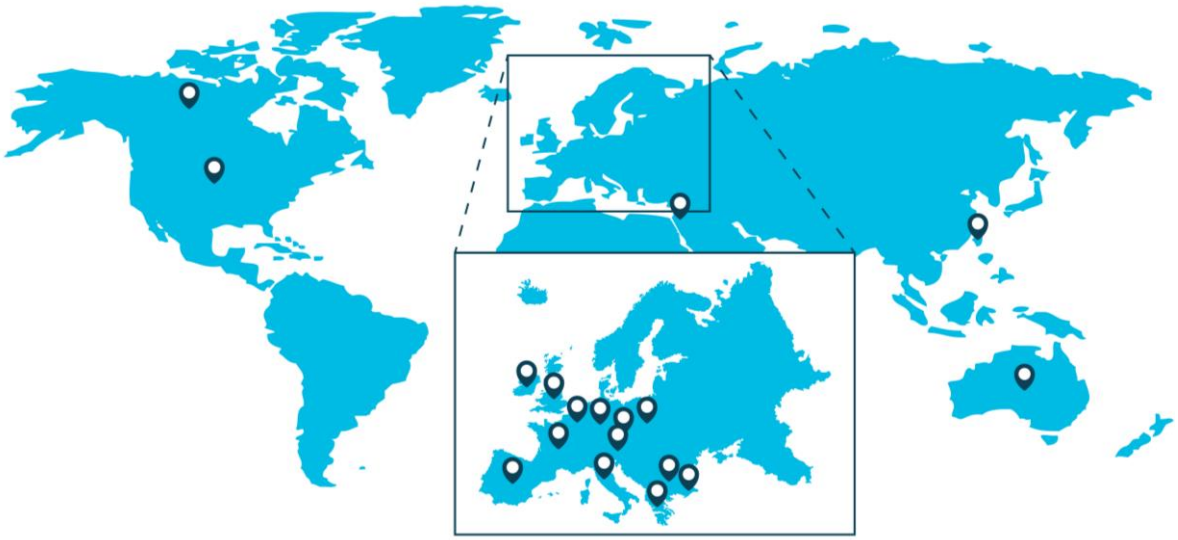
Who took part in the study?

This study included 75 participants who had participated in the TOWER study. 42 participants (56%, or about 56 out of 100) were men and 33 participants (44%, or about 44 out of 100) were women. At the start of the TOWER study, these participants ranged in age from 19 to 80 years. 37 participants (49%, or about 49 out of 100) were younger than 35 years old, 20 participants (27%, or about 27 out of 100) were 35 to 54 years old, 10 participants (13%, or about 13 out of 100) were 55 to 64 years old, and 8 participants (11%, or about 11 out of 100) were at least 65 years old.





This study took place at 43 study centers across 18 countries. The numbers of participants in each country are shown below.



ASIA
Israel: 1 *(1%)*
Taiwan: 3 *(4%)*

AUSTRALIA
Australia: 5 *(7%)*

EUROPE
Austria: 2 *(3%)*
Belgium: 5 *(7%)*
Bulgaria: 1 *(1%)*
Czech Republic: 6 *(8%)*
France: 7 *(9%)*
Germany: 5 *(7%)*
Greece: 2 *(3%)*
Ireland: 1 *(1%)*
Italy: 14 *(19%)*
Poland: 2 *(3%)*
Spain: 6 *(8%)*
Turkey: 1 *(1%)*
United Kingdom: 1 *(1%)*

NORTH AMERICA
Canada: 7 *(9%)*
United States: 6 *(8%)*

Participants who were still alive and participating at the end of the TOWER study were eligible to join this study.

5. Which Medicines Were Studied?

Blinatumomab and standard chemotherapy were the medicines evaluated in the TOWER study, but participants did not receive any medicine in this study or come to any study visits. Instead, researchers contacted the participants and/or their families who were alive at the end of the TOWER study, and checked their medical charts. The researchers asked whether the participants were still alive, and for participants who received chemotherapy in the TOWER study, whether they had taken blinatumomab after the TOWER study ended.

6. What Were the Side Effects?

All medicines can cause side effects, or unwanted medical problems that may happen when you take a medicine. During the TOWER study, researchers collected information on and reported all the medical problems participants had. For this study, researchers only collected specific information on whether participants were still alive, and for the participants who received chemotherapy in the TOWER study, whether they had taken blinatumomab after the TOWER study ended, so additional information on medical problems was not reported.

7. What Were the Overall Results of the Study?

Did participants who received blinatumomab in the TOWER study live longer than participants who received standard chemotherapy in the TOWER study?

- This study found that half of the participants who received standard chemotherapy in the TOWER study lived at least 4 months. Half of the participants who received blinatumomab in the TOWER study lived at least 7.6 months.
- A total of 12 out of 134 participants (9%, or about 9 out of 100) who received standard chemotherapy during the TOWER study switched to blinatumomab.

4 of these participants were recorded as switching to blinatumomab during this study.

- This study was completed as planned.

8. How Has This Study Helped Participants and Researchers?

What else is important to know about these results?

These results are only for this clinical study, which looked at a sample of 75 people with ALL. Not all participants in the study had the same results. The results for any single participant could have been better or worse than the results for their group. Other studies may find different results. These results do not explain how a medicine may work in a single person. Many studies are needed to show the benefits and risks of a medicine that is still being tested. This research may help future participants and families by helping doctors understand more about the treatment being studied.

9. Are There Plans for Further Studies?

If more clinical studies are done, they may be listed on public websites, such as those below. Search for blinatumomab on the websites below.

10. Where Can I Find More Information About This Study?

To find out more about this study, check these websites:

- www.clinicaltrials.gov.
- www.clinicaltrialsregister.eu

If you participated in the study and have questions about the study results, the doctor or staff at your study site may be able to answer them.