Please note that this summary only contains information from the full scientific abstract: **View ASH Abstract**

Estimating the efficacy and cost-effectiveness of inotuzumab ozogamicin and blinatumomab in people with acute lymphoblastic leukemia

Date of summary: December 2019
Study number 1: NCT01564784 | **Study start date:** August 2012 | **Study end date:** January 2017
Study number 2: NCT02013167 | **Study start date:** January 2014 | **Study end date:** March 2017

The full title of this abstract is: Estimating the relative treatment effect and corresponding cost-effectiveness estimates of inotuzumab ozogamicin vs. blinatumomab for adults with Philadelphia chromosome-negative (Ph-)relapsed/refractory (R/R) B-cell acute lymphoblastic leukaemia (B-ALL) in the United Kingdom (UK).

These study drugs are approved in the United States to treat the condition discussed in this summary.

Researchers must look at the results of many types of studies to understand whether a study drug works, how it works, and whether it is safe to prescribe to patients.

This summary reports the results of two studies. The results of this study might be different from the results of other studies that the researchers look at.

More information can be found in the scientific abstract of this study, which you can access here:
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Click to find out how to say tricky medical terms

- **Acute lymphoblastic leukemia** <uh-KYOOT LIM-foh-BLAS-tik loo-KEE-mee-uh>
- **ALL** <A-ell-ell>
- **Blinatumomab** <Blih-nuh-TOO-moh-mab>
- **Inotuzumab ozogamicin** <in-noh-TOO-zoo-mab OH-zoh-ga-MIH-sin>
- **Lymphoblast** <LIM-foh-BLAST>

What did this study look at?

- Acute lymphoblastic leukemia (ALL for short) is a type of blood cancer. In ALL, the body makes too many of a type of white blood cell called a lymphoblast.
  - In some people, the cancer can become undetectable, but then come back (known as a relapsed ALL) or the cancer can stop responding to treatment (known as refractory ALL).
- Inotuzumab ozogamicin (InO for short) is a treatment for people with relapsed or refractory ALL (R/R ALL for short).
  - Some lymphoblasts have a protein called CD22 on their surface.
  - InO works by finding the cells with CD22 and helping the body's immune system to destroy them.
- Blinatumomab (Blina for short) is another treatment for people with R/R ALL.
  - Some lymphoblasts have a protein called CD19 on their surface.
  - Blina works by finding the ALL cancer cells with CD19 and helping the body's immune system to destroy them.
- People with ALL who have a complete response to the treatment can sometimes then receive a stem cell transplant.
  - A complete response means that no signs or symptoms of cancer are detectable. However, this does not always mean that the cancer is completely gone.
- During a stem cell transplant, a person with ALL receives stem cells from a healthy person. These cells will produce healthy blood cells, including lymphoblasts.
  - Stem cell transplants are currently the only treatment for R/R ALL that is effective in the long term.
- Although there are studies comparing InO or Blina to other treatments, there are no studies that directly compare InO and Blina in people with R/R ALL.
- In this study, researchers used several mathematical modeling methods to estimate the outcomes for people who received InO or Blina as if they had taken part in the same study.
- Researchers wanted to know:
  - How many people with R/R ALL who received InO had a complete response compared to people who received Blina.
  - How many people with R/R ALL who received InO had a stem cell transplant compared to people who received Blina.
  - How long people with R/R ALL who received InO lived compared to people who received Blina.
  - How cost-effective treatment with InO was compared to treatment with Blina.
- This summary describes estimated differences in the efficacy* and cost-effectiveness** of InO and Blina. The cost information is based on the health system used in the United Kingdom where the currency is pound sterling (£).

* Efficacy is how well a drug works within a clinical trial.
** Cost-effectiveness describes the value received for the money spent on a treatment. The researchers looked at how much each of the treatments cost and how much they improved people's quality of life and survival.

Who took part in this study?

- Researchers compared information from two different clinical studies:
  - Study 1 looked at people with R/R ALL who received InO.
  - Study 2 looked at people with R/R ALL who received Blina.

What were the results of the study?

Comparing outcomes for InO and Blina

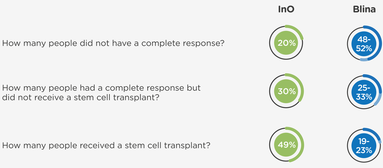
- Comparisons based on information from different trials are called indirect comparisons. These can provide information on differences between treatments.
- Results of this study are from mathematical modeling. The only way to accurately compare the effects of InO and Blina is to look at both treatments side-by-side in the same study.

How likely where people to have a complete response?

For every patient who received Blina and had a complete response, there were likely to be 3 patients who received InO and had a complete response.

How likely where people to receive a stem cell transplant?

For every patient who received Blina and had a complete response, there were likely to be 3 to 4 patients who received InO and had a complete response.



The estimated percentages for Blina varied depending on the mathematical model used.

Looking at cost-effectiveness data, the researchers estimated that people who received **InO** lived at least 29 months longer than those who received **Blina**.
This is likely due to the fact that more people who received **InO** had a stem cell transplant than people who received **Blina**.

- Researchers estimated that InO treatment would cost between £3,700 and £7,010 more than Blina for each additional year of life in good health.
- The estimates from the mathematical model suggest InO was more cost-effective than Blina if there was a willingness to pay £20,000 per year of life in good health.

More results from this study can be found here:
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What were the main conclusions reported by the researchers?

- This indirect comparison of research studies using mathematical modeling suggested that people with R/R ALL who receive InO may live longer than people who receive Blina.
- People with relapsed or refractory ALL who received InO were more likely to have a complete response and to receive a stem cell transplant than people who received Blina.
- In addition, the researchers found that InO was more cost-effective than Blina.

Who sponsored this study?

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Pfizer would like to thank all of the people who took part in this study.

Further information

Click to show more information on the study and clinical trials in general

For more information on this study, please visit:
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Study 1: https://clinicaltrials.gov/ct2/show/NCT01564784
Study 2: https://clinicaltrials.gov/ct2/show/NCT02013167

For more information on clinical studies in general, please visit:
https://www.clinicaltrials.gov/ct2/about-studies/learn
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