

Efficacy and safety of bosutinib in people with chronic myeloid leukemia and additional medical conditions

Date of summary: December 2019

Study number: NCT02228382 | Study start date: November 2014 | Estimated study end date: September 2021

The full title of this abstract is: Efficacy and Safety of Bosutinib by Charlson Comorbidity Index in Previously Treated Patients With Chronic Myeloid Leukemia: Results From the Phase 4 BYOND Study

This study drug is approved to treat the condition under study that is 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 only one study. 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:
[View ASH Abstract](#)

Click to find out how to say tricky medical terms ^

- Bosutinib** <boh-SOO-tih-nib>
- Myeloid leukemia** <MY-eh-loyd loo-KEE-mee-ah>
- Tyrosine kinase inhibitor** <TY-ruh-seen KY-nays-in-HIH-bih-ter>

What did this study look at?

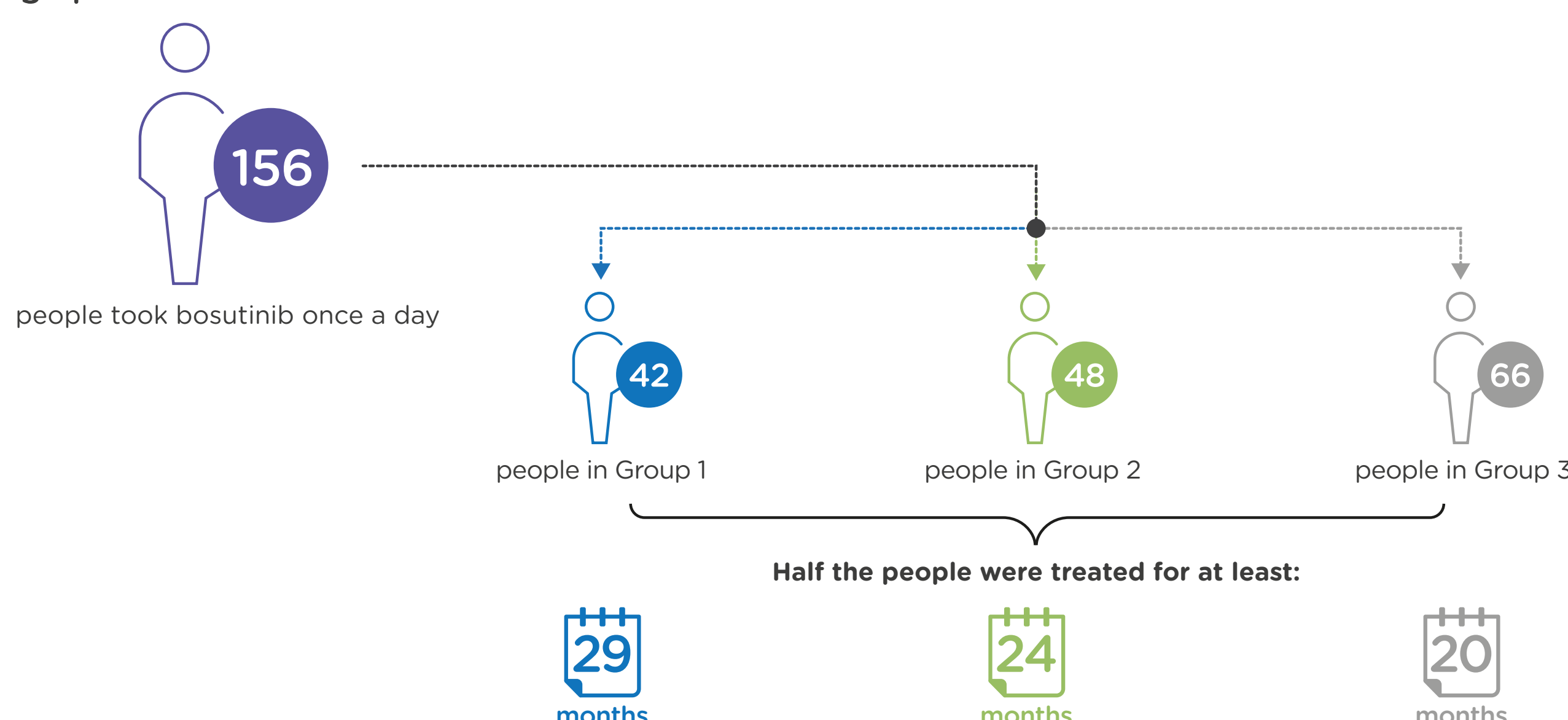
- Chronic myeloid leukemia (CML for short) is a type of cancer that affects white blood cells. It tends to progress slowly over many years.
 - CML is caused by an alteration in a gene called BCR-ABL, which causes the cancer cells to increase in number.
 - Genes are segments of DNA* and are found in structures called chromosomes within each cell of the body. BCR-ABL is found in a chromosome called the Philadelphia chromosome (Ph chromosome for short), which is present in some types of leukemia cancer cells.
- Bosutinib is a type of medicine known as a tyrosine kinase inhibitor (TKI for short).
 - Tyrosine kinases are proteins in the body that control how cells grow and divide.
 - Bosutinib works by blocking tyrosine kinase in the cancer cells, causing them to die.
 - Bosutinib is an approved treatment for people who:
 - have newly diagnosed CML
 - have CML that is no longer responding to treatment with other TKIs or
 - have discontinued prior treatment because they could not tolerate it.
- In this study, people with CML who had already received 1 to 3 previous TKI treatments took bosutinib. These people had CML that was no longer responding to treatment, or they could no longer tolerate their previous TKI treatment.
- This summary looks at whether having additional medical conditions at the start of taking bosutinib affects the efficacy** and safety of bosutinib in this group of people.

* DNA contains genetic information that regulates activity inside a cell.
** Efficacy is how well a drug works within a clinical trial.

Who took part in this study?

- Researchers split people with CML into 3 groups depending on their age, and the number and severity of additional medical conditions they had that might affect their survival.
 - People in Group 3 were older, or had more medical conditions, or their additional medical conditions were more severe than people in Groups 1 and 2.
 - People in Group 1 could have CML only, with no additional medical conditions.
- Researchers monitored people for at least 1 year.

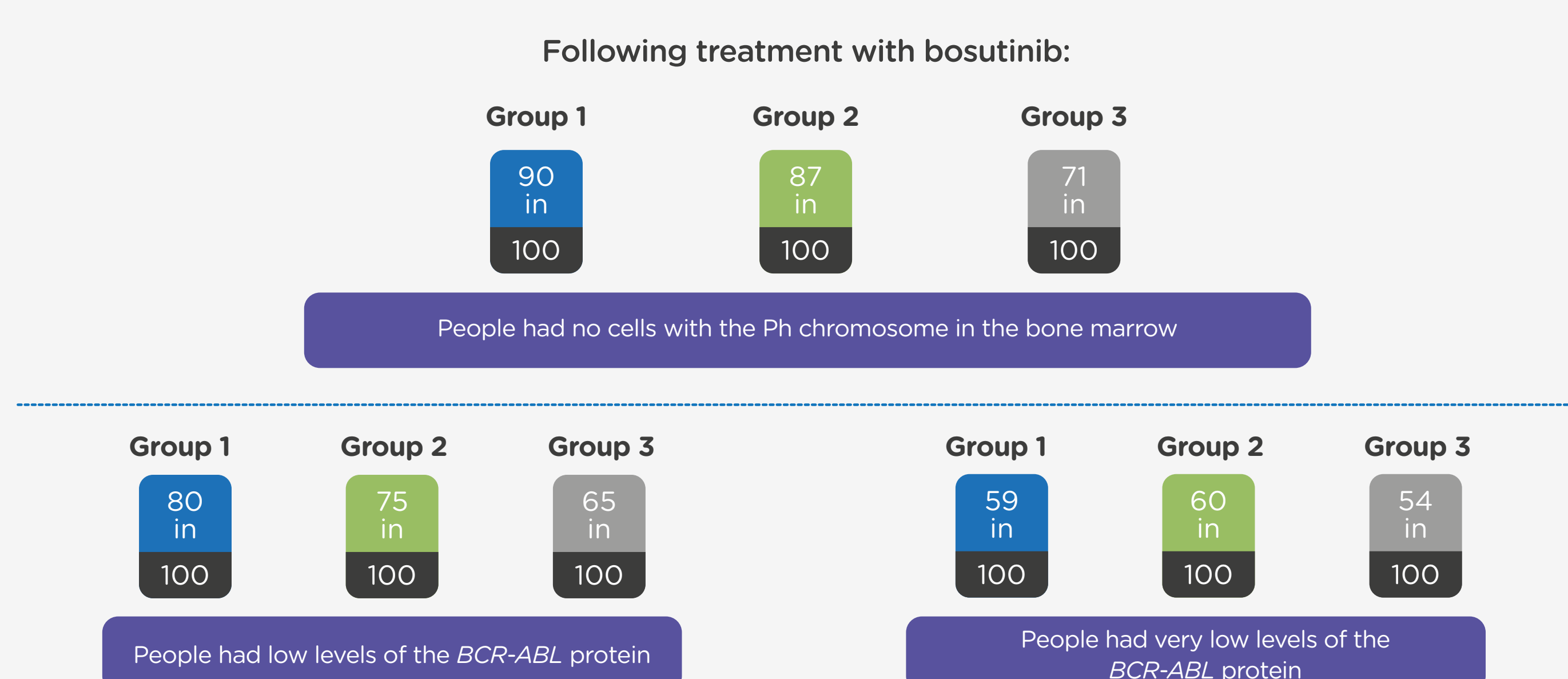
Demographics



What were the results of the study?

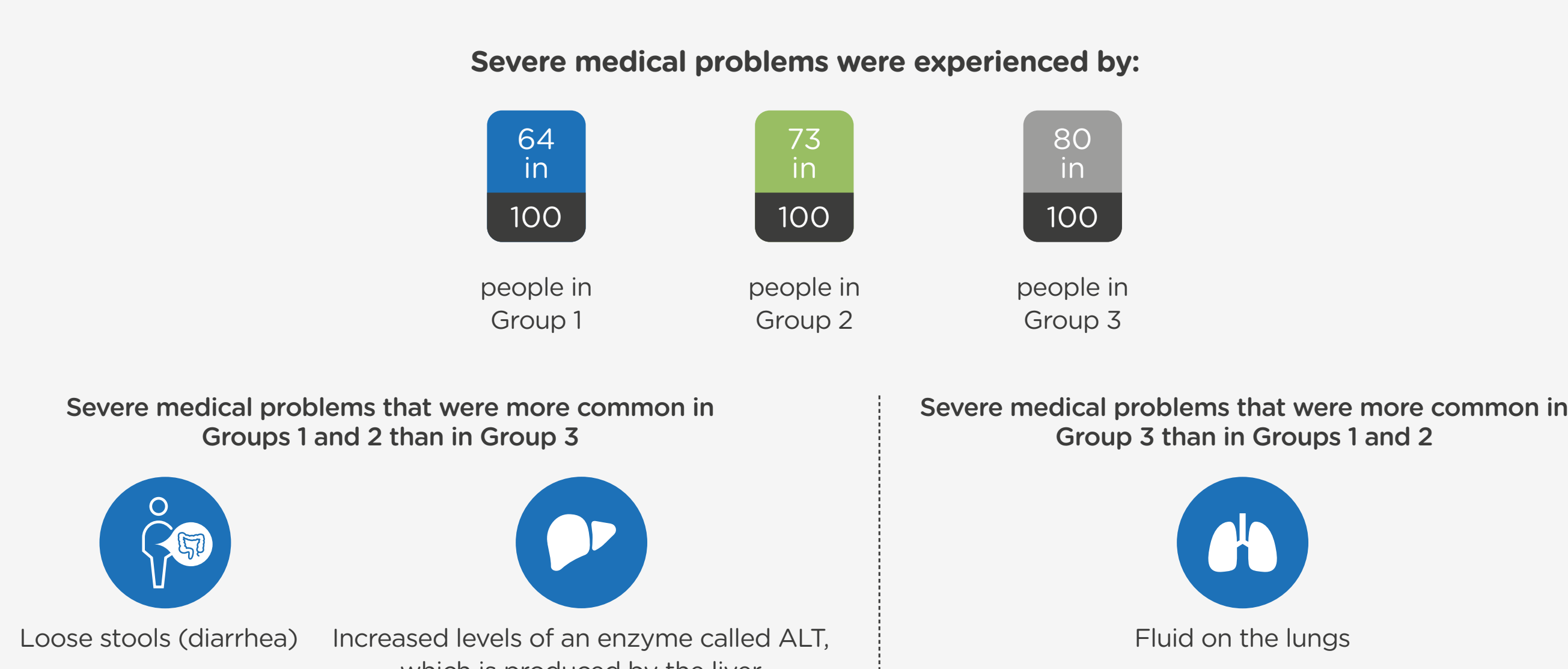
Efficacy

- Researchers looked at whether treatment with bosutinib lowered:
 - the proportion of cells with the Ph chromosome in the bone marrow, and
 - the level of the BCR-ABL protein in the blood.
- These tests show how well bosutinib is working.



Safety

- Of 10 people who died during the study, 9 were in Group 3.
 - 8 of the deaths were due to medical problems*** that were not related to bosutinib, 1 was related to CML, and 1 was of unknown cause.
- More than 60 in 100 people in each group experienced severe medical problems**** during the study.

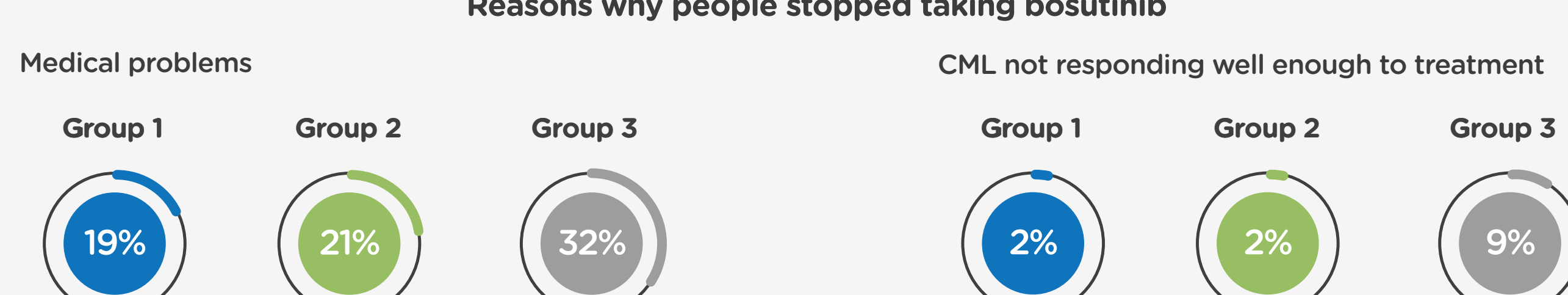


***Medical problems could be caused by reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could have been caused by a study treatment, or by another medicine the participant was taking.

**** A medical problem is considered "severe" when it limits daily activities such as bathing and dressing, is disabling or is medically significant, or could be life-threatening, need hospital care, or cause lasting problems.

- Some people stopped taking bosutinib during the study because of these medical problems or because their CML was not responding well enough to treatment.
 - This was more common for people in Group 3.

Reasons why people stopped taking bosutinib



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

- In this study, most people responded to bosutinib treatment, even when they had additional medical conditions.
- These results suggest that when taking bosutinib, people in Group 3 may:
 - experience severe medical problems more often, and
 - be more likely to stop their treatment because of these medical problems.
- These results may help doctors to identify those people with CML who may need to be monitored more closely when they take bosutinib.

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:

[View ASH Abstract](#)
<https://clinicaltrials.gov/ct2/show/NCT02228382>

For more information on clinical studies in general, please visit:

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