

Safety of bosutinib in people with chronic myeloid leukemia who have received previous treatment

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: Cross-Intolerance With Bosutinib After Prior Tyrosine Kinase Inhibitors in Patients With Chronic Phase Chronic Myeloid Leukemia: BYOND Phase 4 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.

This summary reports the interim results from the study – results may not be the same when the study is complete.

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>
- Dasatinib** <da-SA-tih-nib>
- Imatinib** <ih-MA-tih-nib>
- Myeloid leukemia** <MY-eh-loyd loo-KEE-mee-ah>
- Nilotinib** <ny-LOH-tih-nib>
- 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, or
 - have CML that is no longer responding to treatment with other TKIs (such as imatinib, dasatinib and nilotinib), or

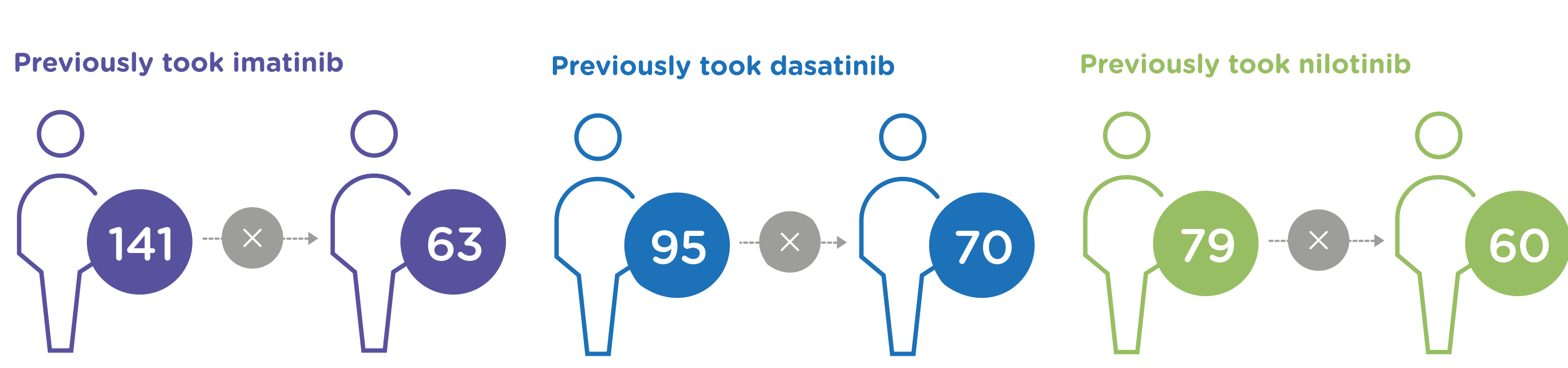
- have discontinued prior treatment because they could not tolerate it.
- Some people have to stop taking one TKI because:
 - They can no longer tolerate treatment due to medical problems* (known as intolerance).
 - They can no longer tolerate treatment due to the same medical problem.
- This ongoing study looks at people with CML who are taking bosutinib. These people previously took other TKIs, but:
 - their CML was no longer responding, or
 - they could no longer tolerate the previous TKIs.
- This summary describes the safety of bosutinib in people with CML who had to stop taking imatinib, dasatinib or nilotinib due to medical problems.

* 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.

Who took part in this study?

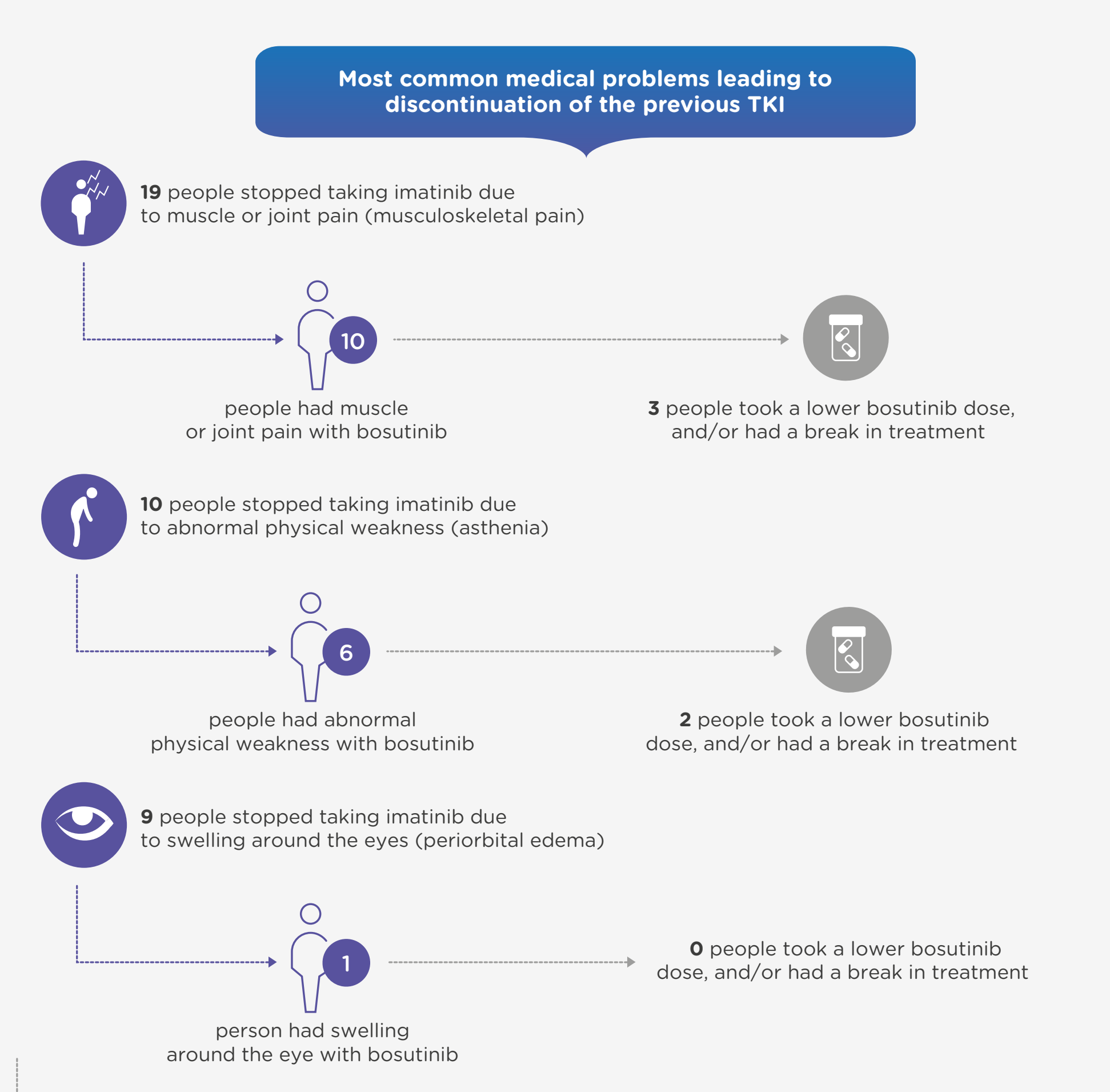
- This analysis looked at 156 people with CML.
 - Some people had received more than one previous TKI.
 - Half of the people included in this study took bosutinib for at least 24 months.

These people stopped taking a previous TKI treatment due to medical problems and then took bosutinib



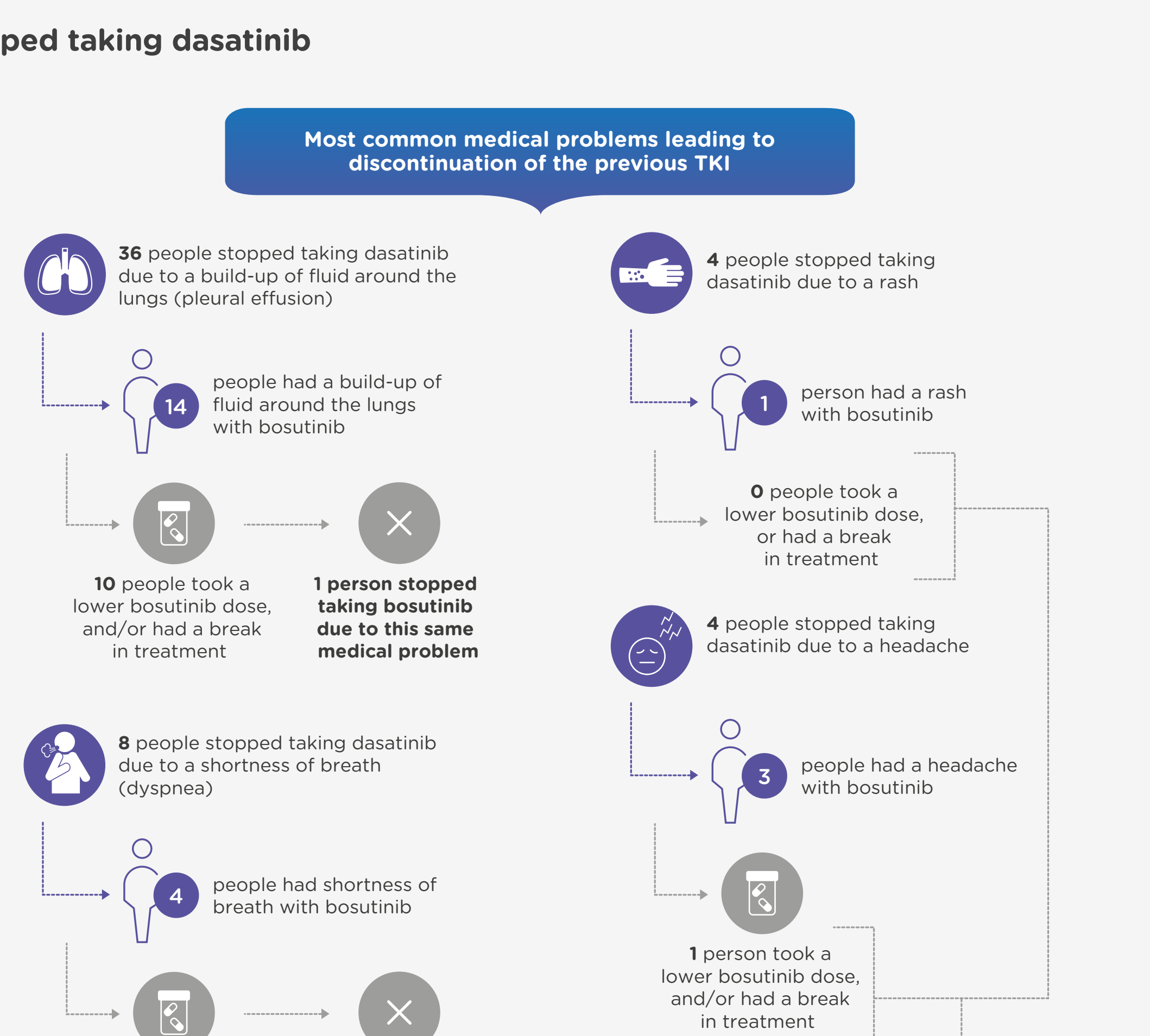
What were the results of the study?

People who stopped taking imatinib



- One person who stopped taking imatinib due to a low number of red blood cells (anemia) also stopped taking bosutinib for the same reason (not shown above).

People who stopped taking dasatinib



- Five people who stopped taking dasatinib also had to stop taking bosutinib because of the same medical problem. These medical problems were as follows:
 - Build-up of fluid around the lungs (pleural effusion), 1 person
 - Shortness of breath (dyspnea), 1 person
 - A low number of red blood cells (anemia), 1 person
 - Feeling sick (nausea), 1 person
 - High blood pressure in the arteries of the lungs (pulmonary hypertension), 1 person

People who stopped taking nilotinib



- No one stopped taking bosutinib because they had the same medical problem that they had with nilotinib.

More results from this study can be found here:

[View ASH Abstract](#)

What were the main conclusions reported by the researchers?

- In this study, only a few people who switched to bosutinib because they could not tolerate the previous TKI had to reduce their dose, delay or stop treatment for the same medical problem.
 - A small number of people taking bosutinib had the same medical problem that came back. These medical problems were managed by reducing the dose and/or taking a break from treatment. In most cases, people were able to continue treatment with bosutinib.
- This study supports bosutinib as a treatment for people with CML who had to stop their previous TKI because they can no longer tolerate it due to medical problems.

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:

<https://www.clinicaltrials.gov/ct2/about-studies/learn>
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