Quality of life in people with chronic myeloid leukemia who take bosutinib

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: Maintenance of Health-Related Quality of Life in the Phase 4 BYOND Study of Bosutinib for Pretreated Chronic Phase Chronic Myeloid Leukemia

Bosutinib 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 \land



- ▲ 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, 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 kinases 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 tyrosine kinase inhibitors (such as imatinib, dasatinib and nilotinib), or

- have stopped their previous treatment because they could not tolerate it.
- In this study, people with CML who had already received from 1 up to 3 previous tyrosine kinase inhibitors took bosutinib. These people either had CML that was no longer responding to treatment, or they could no longer tolerate their previous treatment.
- This summary describes the effect of bosutinib treatment on people's quality of life after 12 months of treatment with bosutinib, compared with their quality of life at the start of treatment.

* DNA contains genetic information that regulates activity inside a cell.



- The questionnaire had 44 questions. Each question was scored on a scale of 0 to 4, with 0 meaning the worst quality of life, and 4 meaning the best quality of life. The researchers looked at the following:
 - Physical well-being
 - Social well-being
 - Emotional well-being
 - Functional well-being (people's ability to perform daily activities e.g. cooking, washing)
 - Well-being related to CML
 - Total score for overall well-being
 - Total score for overall well-being and well-being related to CML
 - Total score for physical well-being, functional well-being, and well-being related to CML
- The researchers looked at how these scores changed over a 12-month period, before and after treatment with bosutinib.
- They then compared the results from the questionnaires at the start of this study and after 12 months with results from an earlier study of bosutinib in people with previously treated CML to see whether there was consistency in the results.

What were the results of the study?

- Before treatment, people who had received 1 or 2 previous tyrosine kinase inhibitors said they had a similar quality of life. There were small differences in some specific areas:
 - People who received 1 previous tyrosine kinase inhibitor experienced poorer social and functional well-being than who received 2 previous tyrosine kinase inhibitors.
- People who received 1 previous tyrosine kinase inhibitors experienced better emotional well-being scores than people who received 2 previous tyrosine kinase inhibitors.
- Before treatment, people who received 3 previous tyrosine kinase inhibitors experienced poorer well-being across all categories than people with 1 or 2 previous tyrosine kinase inhibitor medicines.
- Overall, when the researchers compared the scores at the start of the study with the scores after 12 months of bosutinib treatment, they found there was no change large enough to be considered important. This suggested that people in the study generally maintained the same quality of life while taking bosutinib.



Quality of life is maintained at 12 months of bosutinib treatment in people with CML

• The researchers found that these results were similar to the results of an earlier study of bosutinib, which also lasted 12 months. This consistency helps to confirm these results.

More results from this study can be found here: **View ASH Abstract**

What were the main conclusions reported by the researchers?

- People with CML who took bosutinib for 12 months maintained the same quality of life from the start to the end of treatment. Overall scores at the end of this period did not show any important differences to the scores recorded before treatment started.
 - Maintaining the same quality of life is important for people with CML as they may need to take tyrosine kinase inhibitors for the rest of their lives.
- These results suggest that bosutinib is a well-tolerated treatment option for these people.

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 \land

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 http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are

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