BioDrugs
BIOTECHNOLOGY AND CLINICAL INNOVATION

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PEER-REVIEWED
PLAIN LANGUAGE
SUMMARY

PF-05280586 (Ruxience™) and originator rituximab (MabThera®) had similar efficacy and safety in people with follicular lymphoma

Date of summary: November 2019

Disclaimers

- This study was sponsored by Pfizer.
- The rituximab biosimilar, PF-05280586, is not approved to treat the condition under study that is discussed in this summary. The originator version of rituximab is approved to treat the condition under study that is discussed in this summary.
- Researchers need to generate data and conduct one or more studies to show that biosimilars have a similar safety profile and are as effective as the originator products, with the same expected benefits and risks for people who receive them.
- 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.

Phonetics

- Rituximab <rih-TUK-sih-mab>
- Follicular lymphoma <fuh-LIH-kyoo-ler lim-FOH-muh>

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Study background

- CD20-positive low-tumor-burden follicular lymphoma is a type of blood cancer.
  - CD20-positive means that the cancer cells have a protein called CD20 on their surface.
  - Low tumor burden means that the amount of cancer in the body is low.
- Rituximab (also called MabThera®) is a drug that attaches to the CD20 protein on follicular lymphoma cells. This allows the cells to be destroyed by the body's immune system, slowing down the spread of cancer.
  - Rituximab is a biologic medicine, which means it is produced from living things or contains parts of living things.
- PF-05280586 is a rituximab biosimilar.
  - Biosimilars are medicines that are very similar to existing biologic medicines (called the originator) such as rituximab.
  - The availability of biosimilars increases treatment options for people with certain diseases.
- The study looked at whether PF-05280586 has similar efficacy and safety compared with originator rituximab in people with CD20-positive low-tumor-burden follicular lymphoma, after 1 year of treatment.
  - Efficacy is how well a drug works within a clinical trial.

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Study participants

- Researchers studied 394 people with CD20-positive low-tumor-burden follicular lymphoma.
  - 196 people received PF-05280586 and 198 people received originator rituximab.

Study results

Efficacy

- At 6 months, around 8 in 10 people who received PF-05280586 and around 7 in 10 people who received originator rituximab had cancer that had shrunk or disappeared.
  - Researchers estimated that at 1 year, the proportion of people living with cancer that had not worsened was similar in both treatment groups (around 8 in 10 people).
  - Based on the similarity of these results, researchers concluded that PF-05280586 had similar efficacy to originator rituximab for treating CD20-positive low-tumor-burden follicular lymphoma.

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Study results

Safety

- The safety profiles of PF-05280586 and originator rituximab were similar.
  - Around 8 in 10 people who received PF-05280586 and around 7 in 10 people who received originator rituximab experienced a medical problem.
    - Medical problems can be caused by reasons not related to the study, study treatment, or another medicine the person was taking.
  - The most common medical problems experienced by people taking PF-05280586 or originator rituximab were medical problems related to the treatment infusion, itchy skin, and headache.
  - Around 1 in 10 people in both groups had a serious medical problem related to the study treatment.
    - A medical problem is considered “serious” when it is life-threatening, needs hospital care or causes lasting problems.
- PF-05280586 and originator rituximab behaved in a similar way in the body and triggered the same kind of responses by people’s immune systems.

Study conclusions

- This study showed that PF-05280586 and originator rituximab had similar efficacy and safety in people with CD20-positive low-tumor-burden follicular lymphoma.

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Who sponsored these studies?

- The work was sponsored by Pfizer Inc, New York, NY, USA. The sponsors would like to thank everyone who took part in this study.

Further information

- Further information on the clinical trial can be found here: https://clinicaltrials.gov/ct2/show/NCT02213263
- The study started in September 2014 and ended in April 2018.
- You can find the full article here: https://link.springer.com/article/10.1007/s40259-019-00398-7
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