Advances in Therapy

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PEER-REVIEWED PLAIN LANGUAGE SUMMARY

Comparing the Profile of PF-06881894, a Proposed Biosimilar to Pegfilgrastim, With Approved Pegfilgrastim Reference Products From the United States and Europe in Healthy Volunteers

Date of summary: June 2020

The full title of this article is: PF-06881894, a Proposed Biosimilar to Pegfilgrastim, Versus US-Licensed and EU-Approved Pegfilgrastim Reference Products (Neulasta®): Pharmacodynamics, Pharmacokinetics, Immunogenicity, and Safety of Single or Multiple Subcutaneous Doses in Healthy Volunteers

- PF-06881894, a proposed pegfilgrastim biosimilar, is not approved to treat the condition that is discussed in this summary.* The reference versions of pegfilgrastim are approved to treat the condition that is discussed in this summary.
- The results of these studies may differ from those of other studies. Researchers should make treatment decisions based on all available evidence.

* Since publication of the full article, PF-06881894 has been approved as a biosimilar to Neulasta® by the United States Food and Drug Administration.

How to say medical terms used in this summary

- Antibody (AN-tee-BAH-dee)
- Biosimilar (BY-oh-SIH-mih-ler)
- Chemotherapy (Kee-moh-THAYR-uh-pee)
- Neulasta (noo-LA-stuh)
- Neutralizing (NOO-troh-lyz-ing)
- Neutropenia (noo-troh-PEE-nee-uh)
- Neutrophil (NOO-troh-fil)
- Pegfilgrastim (peg-fil-GRAS-tim)
- Pharmacologic (FAR-muh-koh-LAH-jik)

What did these studies look at?

- Following chemotherapy for cancer, some people have lower than normal levels of a certain type of white blood cell called neutrophils. This is called neutropenia.
  - Neutrophils help the body fight infection by destroying harmful bacteria that invade the body. They are made in the bone marrow.
  - People with neutropenia have an increased risk of infections.
- Pegfilgrastim is a biological drug that helps the bone marrow make more white blood cells. This can help reduce the risk of infection in people receiving chemotherapy and those who have developed neutropenia.
- PF-06881894 is a proposed pegfilgrastim biosimilar.
  - Biosimilars are medicines that are highly similar to existing biological medicines (called reference products). The pegfilgrastim reference product is called Neulasta®.
  - Biosimilars usually cost less than reference products. Having access to biosimilars increases treatment options for people with certain conditions.
- Researchers need to prove that biosimilars have a similar safety profile and effectiveness as their reference products.

What did these studies look at? (continued)

Two studies (C1221001 and C1221005) compared PF-06881894 with pegfilgrastim reference products.

- The reference products were from the United States (US-pegfilgrastim) or Europe (EU-pegfilgrastim).
- People received the study drugs as an injection beneath the skin.

This summary describes the following:

- Pharmacologic effects (tested only in study C1221001)
  - This means how each study drug affects the body and is processed by the body.
- Immune responses (tested in-depth only in study C1221005)
  - This means whether the body's immune system reacted to the study drugs. Researchers measured this by looking at proteins in the blood called anti-drug antibodies.
    - Anti-drug antibodies can make study drugs less effective.
- Safety
  - The researchers tracked medical problems† during both studies.

† 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 these studies?

- Altogether, 573 healthy people took part in these studies.
  - Healthy people have stronger immune systems. This means that it is easier for researchers to see the effects of drugs in them than in people with weakened immune systems.
  - These people were aged between 18 and 65 years.
  - Around half (46%) were male.
  - Around three-quarters (74%) were white.
- In the pharmacologic study (C1221001), 153 people received a single dose of PF-06881894, US-pegfilgrastim, and EU-pegfilgrastim.
  - They received each drug once during the study.
  - Each drug dose was at least 56 days apart.
- In the immune response study (C1221005), 420 people were assigned to receive 2 doses of either PF-06881894 or US-pegfilgrastim.
  - 210 people received PF-06881894.
  - 210 people received US-pegfilgrastim.
  - Each drug dose was received about 1 month apart.

What were the results of the study?

Pharmacologic effects

- The 3 study drugs, PF-06881894, US-pegfilgrastim, and EU-pegfilgrastim, had a similar effect and were processed in a similar way.
- The researchers tested pharmacologic effects in about 93 out of 100 people in the study.
  - Around 7 in 100 people had antibodies against pegfilgrastim in their blood and were not tested because antibodies can interfere with the results.

Immune responses

- The proportion of people who had an immune response during the study was similar for PF-06881894 and US-pegfilgrastim.
  - Around 6 in 100 people who received PF-06881894 had an immune response.
  - Around 7 in 100 people who received US-pegfilgrastim had an immune response.
- The researchers only tested the immune response in people who did not already have antibodies to the study drug before receiving them.
  - No one in the C1221005 study had a more powerful type of antibody called a neutralizing antibody.

What were the results of the study? (continued)

Safety

- The safety profiles of PF-06881894 and the pegfilgrastim reference products were similar.

Safety in study C1221001

- People who reported at least one medical problem:
  - 99 out of 100 people who received PF-06881894, and
  - 95 out of 100 people who received US-pegfilgrastim or EU-pegfilgrastim.
- The most common medical problems were as follows:
  - Pain in muscles and bones in:
    - 80 out of 100 people who received PF-06881894,
    - 79 out of 100 people who received US-pegfilgrastim, and
    - 75 out of 100 people who received EU-pegfilgrastim.
  - Headaches in:
    - 68 out of 100 people who received PF-06881894 or US-pegfilgrastim, and
    - 71 out of 100 people who received EU-pegfilgrastim.

What were the results of the study? (continued)

Safety in study C1221005

- People who reported at least one medical problem:
  - 92 out of 100 people who received PF-06881894, and
  - 96 out of 100 people who received US-pegfilgrastim.
- The most common medical problems were as follows:
  - Back pain in:
    - 59 out of 100 people who received PF-06881894, and
    - 60 out of 100 people who received US-pegfilgrastim.
  - Headache in:
    - 53 out of 100 people who received PF-06881894, and
    - 51 out of 100 people who received US-pegfilgrastim.
- The presence of antibodies against pegfilgrastim did not affect the safety of either study drug.

What were the main conclusions reported by the researchers?

- In these studies, PF-06881894, a proposed pegfilgrastim biosimilar, was similar in terms of its:
  - pharmacologic effects compared with US- and EU-pegfilgrastim reference products in study C1221001,
  - immune response compared with US-pegfilgrastim in study C1221005, and
  - overall safety compared with US- and EU-pegfilgrastim reference products.

Who sponsored these studies?

Study C1221001 was sponsored by Hospira Inc, which was acquired by Pfizer in September 2015, and by Pfizer. Study C1221005 was sponsored by Pfizer.

Pfizer

235 East 42nd Street NY, NY 10017

Phone (United States): +1 212-733-2323

Further information

Further information on the clinical trials can be found here:

- Study C1221001 (started Aug 2015, completed Jun 2016): https://clinicaltrials.gov/ct2/show/NCT02629289
- Study C1221005 (started Oct 2017, completed Jul 2018): https://clinicaltrials.gov/ct2/show/NCT03273842

You can find the full article here:
https://link.springer.com/article/10.1007/s12325-020-01387-x
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