ABP501 is similar to originator adalimumab in clinical efficacy, safety, and immunogenicity

INTRODUCTION
Rheumatoid arthritis is a chronic inflammatory disease that affects a person’s joints, causing pain and disability. It can also affect internal organs. Rheumatoid arthritis is more common in older people, but there is also a high prevalence in young adults, adolescents and even children, and it affects women more frequently than men.
A biosimilar is a drug that has been developed and approved as a copy of an existing biologic medicine. Because biologic medicines are made from complex proteins, there are special guidelines for making sure that new biosimilars are very similar to the original version, and that they have no important differences in how well they work or what side effects there might be.
The original (sometimes called the ‘reference product’ or originator) adalimumab was launched in the 2000s under the brand name HUMIRA. Adalimumab has been shown to have significant efficacy, and can improve disease activity and quality of life, as well as preventing structural damage to the joints and stopping people having disability. ABP501 has been developed to be similar to the original adalimumab.

WHAT DID THE AUTHORS HOPE TO FIND?
The authors wanted to show that ABP501 was equivalent to the original adalimumab in people with rheumatoid arthritis who still had symptoms even though they had been taking a drug called methotrexate. Being ‘equivalent’ means that it would work as well as the original.

WHO WAS STUDIED?
The study looked at 526 people with rheumatoid arthritis. Everyone was aged between 18 and 80 and had been diagnosed with moderate or severe rheumatoid arthritis for at least 3 months. Everyone included had been taking a drug called methotrexate for at least 3 months without seeing an improvement in their disease symptoms. People were not allowed to take part in the study if they had ever taken adalimumab before, or if they had tried two or more other kinds of biologic medicine.

HOW WAS THE STUDY CONDUCTED?
This was a randomised, double-blind clinical trial. This means that people were assigned by chance to one of two treatment groups. Using chance in this way means that the groups will be similar and will allow the treatment under investigation to be compared objectively.
Half the people in the trial received original adalimumab, and half received the biosimilar ABP501. During the study neither the patients nor their doctors knew which drug they were taking. The study lasted for 6 months.

WHAT WERE THE MAIN FINDINGS OF THE STUDY?
The study showed that ABP501 was equivalent to original adalimumab. Very similar numbers of people (around three-quarters) had an improvement in their disease as measured using ACR20 – a tool designed by the American College of Rheumatology to show how well a treatment works on the signs and symptoms of rheumatoid arthritis. Disease activity scores were also similar when measured with other tools.
There were no differences in side effects between the two groups. There was also no difference in the numbers of people who developed antibodies against the drugs (also called immunogenicity) – which can cause the drugs to stop working or make it more likely that they will get side effects.

ARE THESE FINDINGS NEW?
Yes, this is the first time that ABP501 has been studied in people with rheumatoid arthritis. Previous studies have tested the drug in healthy volunteers.
WHAT ARE THE LIMITATIONS OF THE STUDY?

One limitation of the study is that it was quite short. A follow-up study is ongoing that will collect data up to 72 weeks to see if ABP501 carries on working and whether there are any more side effects when people are treated for longer periods. The study also did not use any X-ray imaging to look inside people’s joints and see if the drugs were slowing down or stopping underlying joint damage.

WHAT DO THE AUTHORS PLAN ON DOING WITH THIS INFORMATION?

The results of this study have been used to get approval of ABP501 in Europe and the United States. ABP501 is the first biosimilar adalimumab that has been approved for use and more biosimilar adalimumabs have now been approved or will most likely be approved in the near future. This situation is expected to create more competition and lead to lower prices and hopefully better access to this important, effective but also expensive adalimumab drug in many countries. As well as rheumatoid arthritis, the approval has been extended so that ABP501 can also be used for people who have psoriasis, psoriatic arthritis, ankylosing spondylitis, or inflammatory bowel disease.

WHAT DOES THIS MEAN FOR ME?

It is expected that biosimilars will be less expensive than original/reference biologics. If you pay for your own treatment, this could save you money. Where treatment is paid for by the government, it could mean that more people are able to receive treatment from the same budget.

If you are interested in receiving a biosimilar, or if you have questions about your treatment, you should speak to your rheumatologist or doctor.

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