

## Ixekizumab: a new treatment option for people with PsA



Ixekizumab treatment resulted in improvements in disease activity and physical function in people with PsA.

### INTRODUCTION

Psoriatic arthritis (often shortened to PsA) is a chronic inflammatory disease that affects a person's joints, causing pain and disability. The disease often causes swelling of the fingers and toes. It gets its name from the link between this type of arthritis and a skin condition called psoriasis, which causes redness and scaling. PsA can be progressive and destructive. It can cause a reduction in people's quality of life and a risk of dying earlier than people without the disease.

Ixekizumab is a new drug being tested for PsA. It is a type of medicine known as a biologic disease-modifying antirheumatic drugs (bDMARD or biologic). It works by blocking a molecule called interleukin-17 (also called IL-17) that is involved in inflammation and the development of PsA and psoriasis.

### WHAT DID THE AUTHORS HOPE TO FIND?

Ixekizumab has already been studied in people with psoriasis, where it was found to be better than another biologic drug called etanercept (brand name Enbrel).<sup>1,2</sup> In this new study called SPIRIT-P1 the authors wanted to find out whether ixekizumab worked better than placebo (a dummy drug) in people with PsA, and if it could stop people getting damage in their joints.

### WHO WAS STUDIED?

SPIRIT-P1 looked at 417 people from different regions and countries all over the world. Everyone had PsA, rather than any other type of arthritis, and nobody had used any other biologic drug before. Of the people included in the study, most (70%) had psoriasis covering at least 3% of their body surface area.

### HOW WAS THE STUDY CONDUCTED?

This was a randomised, double-blind trial, which means that patients were assigned by chance to one of four treatment groups. Using chance in this way means that the groups are similar and allows the treatments to be compared objectively. The study lasted for 24 weeks. During this time neither the patients nor their doctors knew which group they were in. The four groups were: an ixekizumab injection every 2 weeks, an ixekizumab injection every 4 weeks, an adalimumab injection every 2 weeks, or placebo (a dummy drug). Anyone taking a stable dose of a conventional DMARD (for example, methotrexate) was allowed to carry on taking that drug as well for the whole of the study.

Everyone was tested to see how well the treatment worked for them (called an ACR response, which measures improvement according to the American College of Rheumatology criteria), as well as whether they had any structural joint damage, or improvements in their physical function. People who had swellings in their fingers or toes or psoriasis patches on their skin at the start of the study were also monitored for improvements in these symptoms.

### WHAT WERE THE MAIN FINDINGS?

The study found that after 24 weeks, significantly more patients treated with ixekizumab achieved a 20% improvement in their ACR response than people who were treated with placebo (30%). This response was detected as early as one week after the first injection. People's physical function was also significantly improved and there was less progression of structural damage, compared to people treated with placebo. Ixekizumab also delivered improvement in skin symptoms, and many people's finger and toe swellings cleared up completely. People treated with adalimumab also did much better than those who got placebo.

Side effects were reported in more people who took ixekizumab or adalimumab than placebo. These side effects were mostly mild or moderate and over 97% of people were able to carry on taking the drug. The most common side effects with ixekizumab were reactions or irritation where the injection was given, or nasopharyngitis (symptoms like a cold). Similar numbers of people in all groups got infections while they were in the study. There were no reports of serious complications such as cardiovascular events or cancers.

### ARE THESE FINDINGS NEW?

Yes. This is the first study published specifically on ixekizumab for PsA. That means that the results are novel. SPIRIT-P1 is unique in terms of PsA studies because it included comparisons with adalimumab (an established treatment for PsA) as well as a placebo group.

### ARE THERE ANY LIMITATIONS?

This part of the study was only 24 weeks. This is because it would not be ethical to give people a placebo for longer than this. The study was also restricted to people who had not taken a biologic therapy before, which means that we cannot generalise the findings to people who have taken a biologic therapy and had no effect, or lost response after initially having a good response to a biologic therapy. Also, the way the study was designed means that it is not possible to demonstrate statistical differences between the two different ixekizumab groups (every 2 or 4 weeks) or to make any comparison between ixekizumab and adalimumab.

### WHAT DO THE AUTHORS PLAN ON DOING WITH THIS INFORMATION?

The study is carrying on with two groups of people (ixekizumab every 2 or 4 weeks). In total, SPIRIT-P1 will collect information for 3 years. More data from these groups at 52 weeks was already presented at the 2016 ACR and EULAR congresses. In addition, there is another study underway in people with PsA who have used biologic therapy before (SPIRIT-P2).

### WHAT DOES THIS MEAN FOR ME?

Ixekizumab is currently not approved for the treatment of PsA in the United States or Europe. However, the results highlighted in this article provide important information about the efficacy and safety of ixekizumab. This information will be needed for any potential approval of ixekizumab as a treatment option for people with PsA, and the drug may be available for you to try in the future.

If you live in Japan, ixekizumab is already approved for use in people with PsA, and so this study will provide useful information for you and your doctor about what to expect from treatment.

### REFERENCES AND FURTHER READING

1. Leonardi, C. *et al.* Anti-interleukin-17 monoclonal antibody ixekizumab in chronic plaque psoriasis. *N Engl J Med* 2012;366:1190–1199.
2. Griffiths, CE. *et al.* Comparison of ixekizumab with etanercept or placebo in moderate-to-severe psoriasis (UNCOVER-2 and UNCOVER-3): results from two phase 3 randomised trials. *Lancet* 2015;386:541–551.

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