MedicalXpress

Biosimilar CT-P13 matches infliximab in improving ankylosing spondylitis disease activity

June 11 2014

New data presented today at the European League Against Rheumatism Annual Congress (EULAR 2014) show that the newly-approved infliximab biosimilar CT-P13 achieves statistically similar improvements in disease activity, disability and mobility in patients with Ankylosing Spondylitis (AS) compared to its original reference product infliximab (INX).[1]

CT-P13 is the world's first biosimilar monoclonal antibody to receive a positive opinion from an advanced and developed nations' regulatory body. According to Dr Won Park, Inha University Hospital, Korea, and lead investigator of the PLANETAS study, "the challenge for biosimilars is to demonstrate similarity in therapeutic effectiveness, safety and immunogenicity to their reference product, not just biochemical and pharmacokinetic equivalence."

"By demonstrating comparable efficacy and safety, the results of our clinical trials should give physicians confidence in using CT-P13 as an alternative treatment option to INX in AS patients," Dr Park added. "This is good news for patients who may previously have had limited access to costly antibody biopharmaceuticals."

AS is a type of chronic arthritis affecting an estimated 1.4 million patients in Europe.[2] In AS, inflammation in the joints and ligaments causes pain and stiffness in the neck, back and buttocks. The cause of

AS is unknown, and there is no known cure, so the current aim of treatment is to reduce pain and stiffness and to keep the spine flexible.[3]

These new data captured clinical measures of disease activity via ASAS20/40 and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), disability via the Bath Ankylosing Spondylitis Functional Index (BASFI) and mobility via the Bath Ankylosing Spondylitis Metrology Index (BASMI). In addition, the Student's t test was used to compare mean change of three indices from baseline in both treatment groups.

At week 54, BASDAI improved significantly from baseline in both treatment groups (CT-P13: from 6.74 to 3.78 and INX: from 6.57 to 3.70) and this improvement was similar between groups (difference of means -0.29; CI of the difference -0.91 to 0.32). BASFI and BASMI were also similarly improved: BASFI (CT-P13: from 6.20 to 3.42 and INX: from 6.24 to 3.46) and BASMI (CT-P13: from 4.0 to 2.8 and INX: from 4.1 to 3.2).

In addition, a 50% improvement of the baseline BASDAI (BASDAI50) was achieved in 44.3% for CT-P13 and 46.3% for INX at week 54; the BASDAI50 response rate was comparable between the two groups (p=0.7737).

A second objective of the study was to assess the effect of anti-drug antibody (ADA) on clinical outcomes. The use of biological agents can cause the production of ADA leading to reduced levels of treatment in the blood, impacting treatment response and/or increasing rates of infusion reaction. In the study, the presence of ADA was measured using electrochemiluminescent methodology and clinical responses in all treatment groups were examined in relation to the presence of ADA. Higher ASAS20/40 responses were seen in the ADA negative patients (72.7%/56.5%) compared with ADA positive patients (54.7%/37.7%) at

week 54.

The BASDAI and BASFI improved significantly in the ADA negative subgroup compared to the ADA positive subgroup (BASDAI: -3.13 vs. -2.30 and BASFI: -2.97 vs. -2.18), but no clear association with ADA was seen for BASMI. A greater clinical response was shown in the ADA negative subgroup in all three indices. However, the incidence of the ADA and their magnitude of impact on the clinical response or adverse event were similar between biosimilar CT-P13 and innovator infliximab.

CT-P13 has previously demonstrated pharmacokinetic (PK) equivalence to INX in the PLANETAS trial, a randomised double-blind, parallel group study of 250 patients with AS, and was recently approved by the European Medicines Agency.

More information: Abstract Number: OP0157

Notes:

1 Park W, Yoo DH, Szántó S, et al. Clinical response of disease activity, disability and mobility indices in relation to anti-drug antibody in the Planetas. EULAR 2014; Paris: Abstract OP0157
2 Morton L.. The Prevalence and burden of ankylosing spondylitis in Europe. University of Aberdeen.www.rheumatology.org.uk/includ … yloarthropathies.pdf [Accessed 06/06/2014]
3 National Health Service. Ankylosing spondylitis. www.nhs.uk/conditions/ankylosi … es/introduction.aspx. [Accessed 06/06/2014]

Provided by European League Against Rheumatism