

**Annual European Congress of Rheumatology
(EULAR 2019)**

Madrid, Spain, 12-15 June 2019

**TILDRAKIZUMAB SHOWS PROMISING EFFICACY AND SAFETY IN PSORIATIC
ARTHRITIS**

Significantly more patients achieve PASI 90 and ACR 50 with the anti-interleukin-23p19 monoclonal antibody versus placebo in phase 2B trial¹

Madrid, Spain, 14 June 2019: The results of a phase 2B study presented today at the Annual European Congress of Rheumatology (EULAR 2019) demonstrate superior efficacy and comparable safety of tildrakizumab versus placebo in patients with psoriatic arthritis.¹

By week 24 in the study, a significantly higher proportion of patients receiving tildrakizumab (at any dose) achieved a 90% reduction in Psoriasis Area and Severity Index (PASI 90), and a 50% reduction in American College of Rheumatology response criteria (ACR 50) versus placebo. There were four active treatment groups in which patients received 20mg, 100mg or 200mg tildrakizumab every 12 weeks, or 200mg every four weeks. The response rates improved with increasing dose however the shortening of dosing interval of 200mg from 12 to four weeks did not result in a measurable increase in skin or joint response scores. In patients receiving 200mg tildrakizumab every 12 weeks, 79.6% and 50% achieved PASI 75 and PASI 90 respectively versus 16.7% and 7.1% in the placebo group ($p < 0.0001$).¹

“Our results demonstrate a clear separation between tildrakizumab and placebo as early as eight weeks,” said Philip Mease, MD, MACR, Swedish Medical Center/Providence St. Joseph Health and the University of Washington, Seattle, Washington, USA. “A promising role is suggested for tildrakizumab in the treatment of patients suffering with psoriatic arthritis.”

Psoriatic arthritis is a chronic inflammatory disease that affects the joints, causing pain and disability. Tildrakizumab is a high-affinity, humanised, monoclonal antibody targeting interleukin (IL) 23p19 and is currently approved to treat moderate-to-severe plaque psoriasis.² Current recommendations state that, in psoriatic arthritis patients with peripheral arthritis (one or more tender and swollen joints), biological disease-modifying anti-rheumatic drugs (DMARDs) targeting IL 12/23 or IL-17 pathways may be considered in patients who have had an inadequate response to conventional synthetic DMARDs and for whom tumour necrosis factor inhibitors are not appropriate.³

“We welcome these promising results for tildrakizumab in patients with psoriatic arthritis,” said Professor Hans Bijlsma, President, EULAR. “Extending research into different patient groups may bring benefits that address current unmet needs.”

The 24-week, randomised, double-blind, placebo-controlled, multiple-dose, phase 2B study included 391 adults with psoriatic arthritis who had three or more tender and three or more

swollen joints. Patients were randomised (1:1:1:1:1) to receive tildrakizumab 200mg every four weeks, 200mg, 100mg or 20mg every 12 weeks, or placebo every four weeks. Stable concomitant methotrexate or leflunomide use was permitted but not mandated.¹

Serious adverse events (AEs) occurred in 2.2% of tildrakizumab-treated patients and 2.5% of placebo-treated patients. Treatment-related serious AEs occurred in 0.3% of tildrakizumab-treated patients (as judged by the investigator). The most frequent AEs included nasopharyngitis and diarrhoea with no reports of candidiasis, inflammatory bowel disease, major adverse cardiac events, or malignancy. No patients discontinued treatment due to AEs and no deaths were reported.¹

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NOTES TO EDITORS

For further information on this study, or to request an interview with the study lead, please do not hesitate to contact the EULAR Press Office:

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About Rheumatic and Musculoskeletal Diseases

Rheumatic and musculoskeletal diseases (RMDs) are a diverse group of diseases that commonly affect the joints, but can also affect the muscles, other tissues and internal organs. There are more than 200 different RMDs, affecting both children and adults. They are usually caused by problems of the immune system, inflammation, infections or gradual deterioration of joints, muscle and bones. Many of these diseases are long term and worsen over time. They are typically painful and limit function. In severe cases, RMDs can result in significant disability, having a major impact on both quality of life and life expectancy.⁴

About EULAR

The European League against Rheumatism (EULAR) is the European umbrella organisation representing scientific societies, health professional associations and organisations for people with RMDs. EULAR aims to reduce the burden of RMDs on individuals and society and to improve the treatment, prevention and rehabilitation of RMDs. To this end, EULAR fosters excellence in education and research in the field of rheumatology. It promotes the translation of research advances into daily care and fights for the recognition of the needs of people with RMDs by the EU institutions through advocacy action.

To find out more about the activities of EULAR, visit: www.eular.org

References

- ¹ Mease PJ, Chohan S, Garcia Fructuoso FJ, *et al.* Randomised, double-blind, placebo-controlled, multiple-dose, phase 2b study to demonstrate the safety and efficacy of tildrakizumab, a high-affinity anti-interleukin-23p19 monoclonal antibody, in patients with active psoriatic arthritis. EULAR 2019; Madrid: Abstract LB0002.
- ² Tildrakizumab SmPC. Available at: https://www.ema.europa.eu/en/documents/product-information/ilumetri-epar-product-information_en.pdf [Last accessed May 2019].
- ³ Gossec L, Smolen JS, Ramiro S, *et al.* European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis.* 2016;75(3):499-510.
- ⁴ van der Heijde D, Daikh DI, Betteridge N, *et al.* Common language description of the term rheumatic and musculoskeletal diseases (RMDs) for use in communication with the lay public, healthcare providers and other stakeholders endorsed by the European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR). *Ann Rheum Dis.* 2018 Jun;77(6):829-832.