

Clinical advances in systemic lupus erythematosus

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The results of two studies presented today at the Annual European Congress of Rheumatology (EULAR 2018) demonstrate exciting advances for individuals suffering from systemic lupus erythematosus (SLE). The first is a phase II clinical study of a promising oral treatment, baricitinib. The second demonstrates the effective use of the shingles vaccine in SLE patients who are particularly prone to this infection.

"Novel therapeutic strategies are needed for SLE, which causes significant morbidity and mortality, and so we are delighted to see the positive results from the phase II trial of baricitinib," said Professor Thomas Dörner, Chairperson of the Abstract Selection Committee, EULAR. "In addition, we welcome data on the vaccination of SLE patients against shingles, as currently there is considerable clinical uncertainty around this issue."

SLE is an autoimmune disease that is also referred to as lupus. It typically affects women between the ages of 15 and 50, and symptoms flare up unpredictably. SLE is caused by complicated interactions between the immune system and environmental factors leading to an imbalance in the way the immune system works. This imbalance causes inflammation which, if untreated, can lead to disability and a shortened lifespan. Different factors may trigger SLE in different people, and symptoms may vary considerably. In some the illness is never lifethreatening but can cause chronic skin rashes or arthritis. Others develop potentially life-threatening disease in the kidneys, lungs or heart. Treatment of SLE traditionally involves non-specific anti-inflammatory



or immunosuppressive medications. However, this approach is ineffective in many patients, and can be associated with many undesirable side effects.

Baricitinib provides significant clinical improvements with acceptable benefit/risk profile in SLE patients

Baricitinib is an oral selective inhibitor of Janus kinase (JAK)1 and JAK2 which has been approved for the treatment of rheumatoid arthritis in Europe and Japan. In this phase II study, SLE patients taking baricitinib had a significant improvement in several clinical outcomes compared to placebo.

"Our results demonstrated significant clinical improvements in SLE patients taking baricitinib versus placebo with an acceptable side effect profile," said Daniel Wallace, MD, FACP, MACR, Professor of Medicine, University of California-Los Angeles and Associate Director of the Rheumatology Fellowship Program at Cedars-Sinai Medical Center in Los Angeles, California. "We look forward to progressing baricitinib in further clinical studies as a promising new treatment for people suffering with SLE."

Current biologic agents for SLE target the B-cell due to the importance of autoantibodies in driving the origination and development of the disease. However, the interferon (IFN) pathway and other cytokines (such as IL-23, IL-12 and IL-2) have recently emerged as a promising therapeutic target. By targeting common components of the signalling cascade, such as the JAK-STAT pathway, there may be therapeutic advantages by more complete suppression of IFN and other cytokines in disease-related processes.

This study included 314 patients with SLE receiving stable background therapy who were randomized 1:1:1 to placebo, baricitinib 2- or 4-mg



once daily. Patients on baricitinib 4mg achieved significant resolution of arthritis or rash (SLEDAI-2K[†]) compared with placebo (67% vs 53%, p

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