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CLINICAL INVESTIGATION

NEWS

Highlights from the latest news and research in clinical investigation

Belimumab receives US FDA approval for treatment of systemic lupus

The US FDA has announced the approval of belimumab (Benlysta®), developed by a collaboration between GlaxoSmithKline (GSK) and Human Genome Sciences (HGS), for the treatment of systemic lupus erythematosus (SLE), commonly known as lupus. In clinical trials belimumab successfully met the primary end point of improvement in patient's systemic lupus erythematosus responder index (SRI), a method of assessing disease severity. The approval of belimumab is important news for lupus sufferers, who have been waiting for new treatment options for disease management.

"This is the first drug specifically licenced for lupus in more than 50 years and it is expected to be effective in patients with moderate to severe lupus activity that did not respond to the standard therapy or that had side effects with the standard therapy" comments Ricard Cervera Head of the Department of Autoimmune Diseases, Hospital Clínic, Barcelona, Spain.

Belimumab is approved for the treatment of adult patients with active, autoantibody-positive SLE currently receiving standard therapy, its' efficacy on severe active lupus nephritis or severe active CNS lupus has not been studied and it is not recommended for treatment in these cases. It has also not been studied in combination with other biological treatments or intravenous cyclophosphamide.

SLE, an autoimmune disease, is associated with overactivity of B cells, and elevated levels of B-lymphocyte stimulator (BLyS). BLyS, which was discovered by scientists at HGS, is a protein that promotes B-cell growth and maturation. Belimumab, a human monoclonal antibody, is the first in the novel drug class of BLyS-specific inhibitors. Rather than binding to B cells directly, belimumab binds to BLyS and thus prevents binding of BLyS to B cells, a novel mechanism of action for autoimmune disease therapy.

The multicenter, randomized, Phase III trials, BLISS-52 and BLISS-76, assessed belimumab's efficacy in patients with SLE. BLISS-52 enrolled sufferers over

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