

Belimumab deemed safe for long-term lupus treatment

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For patients with systemic lupus erythematosus, long-term belimumab therapy combined with standard therapy is well tolerated, according to a study published online June 5 in *Arthritis & Rheumatism*.

(HealthDay) -- For patients with systemic lupus erythematosus (SLE), long-term belimumab therapy combined with standard therapy is well tolerated, according to a study published online June 5 in *Arthritis & Rheumatism*.

Joan T. Merrill, M.D., from the Oklahoma Medical Research Foundation in Oklahoma City, and colleagues evaluated the long-term safety profile of belimumab for <u>patients</u> with active SLE. Patients who were randomized to 1, 4, or 10 mg/kg belimumab or placebo and completed a 52-week double-blind study were eligible for a 24-week extension (345 patients). Placebo patients were switched to 10 mg/kg belimumab and belimumab patients continued with their dose or were



switched to 10 mg/kg. Two hundred ninety-six participants who achieved a satisfactory response were allowed to continue in the long-term evaluation of monthly 10 mg/kg belimumab.

The researchers found that, during four-year belimumab exposure, the incidence rates of adverse events (AEs), severe/serious AEs, infusion reactions, infections, malignancies, grades 3/4 laboratory abnormalities, and AE-related discontinuations remained stable or decreased. Arthralgia, upper respiratory tract infection, headache, fatigue, and nausea were the most common AEs. Only one serious infusion reaction occurred during the four-year follow-up. No specific infection type dominated the AEs and serious infection rates decreased from 5.9 to 3.4/100 patient-years.

"Belimumab added to standard therapy was generally well tolerated over four-year treatment for SLE, suggesting that belimumab can be administered long term with an acceptable safety profile," the authors write.

Several authors disclosed financial ties to Human Genome Sciences Inc. and GlaxoSmithKline, both of which funded the study and manufacture belimumab.

More information: Abstract

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