Adding belimumab improves renal outcome in lupus nephritis

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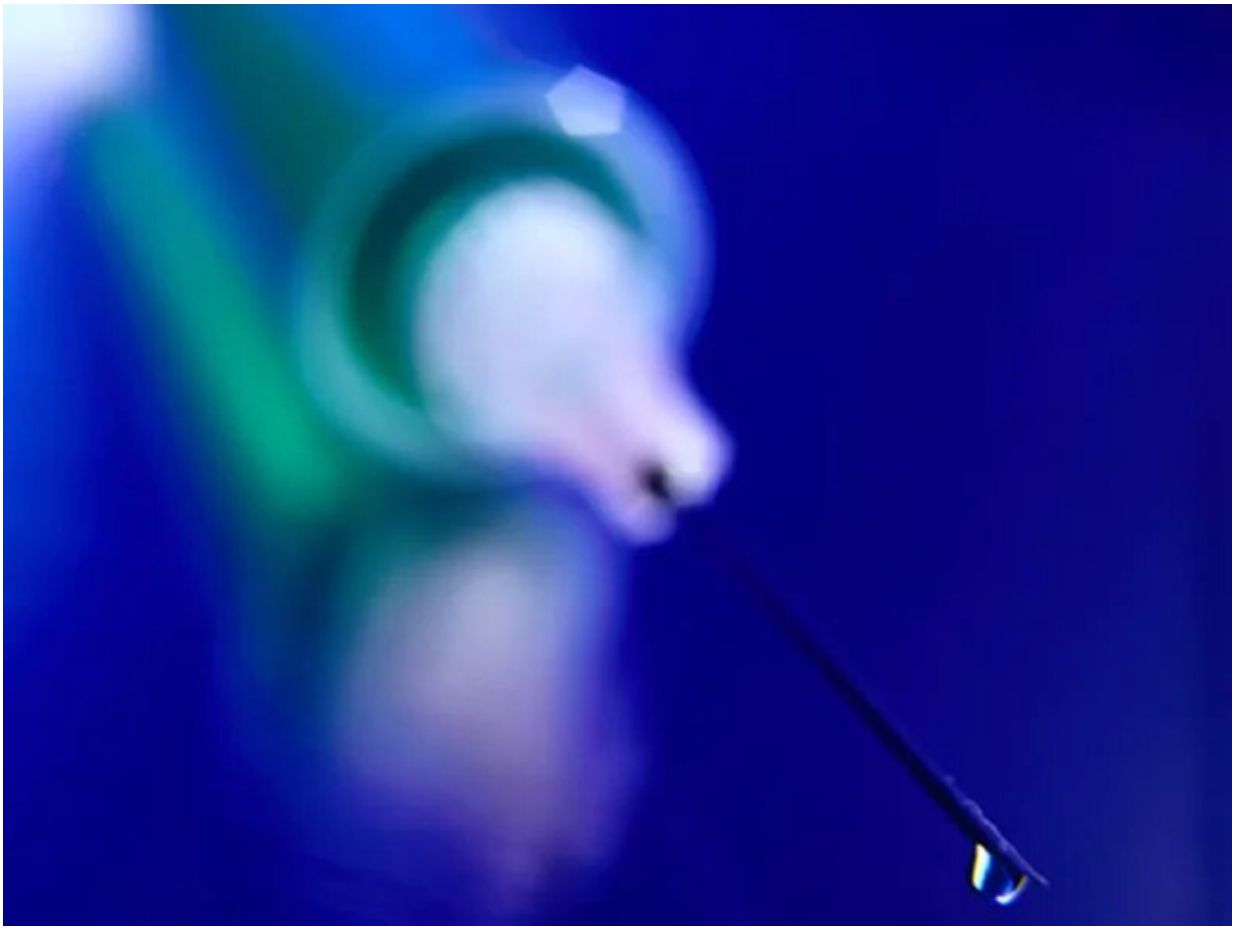

(HealthDay)—The addition of belimumab versus placebo to standard

therapy increases the likelihood of a primary efficacy renal response in patients with active lupus nephritis, according to a study published in the Sept. 17 issue of the *New England Journal of Medicine*.

Richard Furie, M.D., from the Donald and Barbara Zucker School of Medicine at Hofstra-Northwell in Great Neck, New York, and colleagues conducted a 104-week trial at 107 sites in 21 countries involving adults with biopsy-proven, active lupus nephritis. A total of 448 participants were randomly assigned to receive either intravenous belimumab or matching placebo in addition to standard therapy in a 1:1 ratio.

The researchers found that significantly more patients in the belimumab versus placebo group had a primary efficacy renal response (43 versus 32 percent; odds ratio, 1.6; 95 percent confidence interval, 1.0 to 2.3; P = 0.03) and a complete renal response (30 versus 20 percent; odds ratio, 1.7; 95 percent confidence interval, 1.1 to 2.7; P = 0.02) at week 104. Compared with those who received placebo, patients who received belimumab had a lower risk for a renal-related event or death (hazard ratio, 0.51; 95 percent confidence interval, 0.34 to 0.77; P = 0.001).

"This history-making clinical trial is the first successful study after decades of attempts with other lupus nephritis therapies," Furie said in a statement. "This trial will hopefully lead to the U.S. Food and Drug Administration's approval to extend belimumab's use to lupus nephritis, which represents the greatest unmet need for patients with systemic lupus erythematosus."

Several authors disclosed financial ties to pharmaceutical companies, including GlaxoSmithKline, which manufactures belimumab and funded the study.

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