

Lupus treatment generates positive results in Phase III clinical trial

April 20 2018

New research indicates that belimumab, a monoclonal antibody therapy that targets a component of the immune system, provides considerable benefits to patients with systemic lupus erythematosus (SLE), a predominately female, chronic inflammatory disease that can affect virtually any organ. The *Arthritis & Rheumatology* findings are encouraging because lupus is among the leading causes of death in young women.

SLE is a chronic, multisystem autoimmune disorder with a broad range of symptoms, and its development involves defective activation of B cells—the immune cells charged with producing antibodies that attack invading bacteria, viruses, and toxins. B lymphocyte stimulator is a molecule involved in B cell differentiation, and elevated levels may contribute to the production of autoantibodies that target healthy cells and tissues.

To investigate the efficacy and safety of belimumab, which targets B lymphocyte stimulator, Andrea Doria, MD, of the University of Padova, in Italy, and her colleagues conducted a phase III, double-blind, placebo-controlled study that randomized SLE patients 2:1 to weekly subcutaneous injections of belimumab 200 mg or placebo, plus standard lupus therapy, for 52 weeks. Belimumab is currently given by intravenous infusion, but the subcutaneous formulation of has recently become available.

In analyses of 356 patients with certain clinical characteristics indicative

of high disease activity (hypocomplementemic and anti-dsDNA-positive), more patients in the belimumab group experienced reduced lupus disease activity, as measured by what is called the SLE responder index (64.6% versus 47.2%), and there was a lower incidence of severe SLE flares (14.1% versus 31.5%). Also, more people in the belimumab group were able to reduce their need for steroids. Side effects were similar between the groups.

"Intravenous administration of belimumab is an obstacle to treatment for many patients due to the need to go to the hospital for drug infusions. Thus, a higher number of patients could benefit from this treatment," said Dr. Doria. "The self-administration of subcutaneous belimumab makes hospital access unnecessary, which leads to economic savings for [patients](#) and the community."

An accompanying report in *Arthritis & Rheumatology* ranks lupus deaths among the US Centers for Disease Control and Prevention's leading causes-of-death to determine the relative burden of SLE deaths in women. (The agency compiles an annual leading-causes-of-death ranking based on a selected list of 113 causes, but SLE is not included on this list.) The report notes that during 2000-2015, there were 28,411 female deaths in the United States that had SLE recorded as the underlying or contributing cause of death. SLE ranked as the 10th leading cause of death in the 15-24-year age group, 14th in 25-34-year and 35-44-year age groups, and 15th in 10-14-year age group. Among black and Hispanic females, SLE ranked 5th in the 15-24-year, 6th in the 25-34-year, and 8th-9th in the 35-44-year age groups, after excluding three common external injury causes of [death](#) (unintentional injury, homicide, and suicide) from the analysis.

More information: A Doria et al, Efficacy and safety of subcutaneous belimumab in anti-dsDNA-positive, hypocomplementemic patients with systemic lupus erythematosus, *Arthritis & Rheumatology* (2018). [DOI:](#)

[10.1002/art.40511](https://doi.org/10.1002/art.40511)

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Provided by Wiley

Citation: Lupus treatment generates positive results in Phase III clinical trial (2018, April 20)
retrieved 9 April 2024 from
<https://medicalxpress.com/news/2018-04-lupus-treatment-positive-results-phase.html>

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