

Lupus Update with Dr. Robert Katz

What's the latest research on Benlysta?

This past March, the first lupus drug ever was approved by the Food and Drug Administration (FDA) as a treatment for lupus. This landmark decision was the result of years of development and research into the drug, Benlysta's, impact on lupus patients as well as the possible side effects of the drug. Although the drug is approved, research continues into Benlysta, as well as potential new lupus treatments. Now, nearly 9 months after the FDA's approval, how has Benlysta been received and how are other lupus treatments progressing?

An Update on Benlysta

Much of the recent research about Benlysta involved studies done by competent researchers but also the makers of the drug, Human Genome Science. Therefore, to accurately validate these findings, parallel research investigations on Benlysta need to be done in the future.

That said, a study presented at the American College of Rheumatology meeting in Chicago in November, 2011 presented safety data on 2,133 patients with lupus who participated in any Benlysta research study. Benlysta was generally well tolerated with few side effects; there was a small increase in infection rates and infusion reactions in the group of patients taking Benlysta compared with placebo treatment.

In another study of 449 lupus patients taking Benlysta, the research showed sustained improvement in disease activity over 6 years with reductions in steroid use and lower autoantibody levels. In another research paper, patients on Benlysta reported a higher quality of life and reduced fatigue at 52 weeks. Another preliminary study showed improvement in patients with lupus kidney disease.

Answers to Frequently Asked Questions about BENLYSTA

Q: My mother was diagnosed with lupus about eight years ago and suffered from it much longer than that. She is African-American. We have heard that this new drug is not as effective for African-Americans. Could you please advise?

A: The population size of African Americans in the study was not large enough to determine the effectiveness of BENLYSTA in that population. Additional research is planned to evaluate the effectiveness of BENLYSTA on African Americans. That said, it does not mean the drug will not be effective in individual cases, but whether to use BENLYSTA depends on the activity of the lupus and whether it seems like a good idea in an individual patient, so I would not exclude it in your mother's case.

Q: How is the drug different than non-steroidal immunosuppressant drugs like CellCept?

A: Immunosuppressive drugs like CellCept are chemicals made in pharmaceutical factories. CellCept was not developed for lupus and it doesn't target immune cells but rather takes a blanket approach. BENLYSTA is a human monoclonal antibody that specifically recognizes and blocks the biological activity of B-lymphocyte stimulator, a naturally occurring protein. Elevated levels of this protein prolong the survival of B cells which can contribute to the production of autoantibodies – antibodies that target the body's own tissues. Studies have shown that BENLYSTA can reduce autoantibody levels and help control autoimmune disease.

Q: It does not appear that BENLYSTA was tested in a significant Hispanic population.

A: There certainly will be differences in response to BENLYSTA, regardless of ethnicity. This is partly due to genetic and ethnic factors, but also because each case of lupus is unique – cases will be difficult to evaluate. In patients with active lupus, BENLYSTA is a consideration regardless of ethnic background. The patient has to qualify for BENLYSTA by having moderately active lupus.

Q: What interaction, if any, does it [BENLYSTA] have with prednisone or aspirin?

A: BENLYSTA does not have an interaction with prednisone or aspirin. It is okay to use those drugs simultaneously. Many patients hope that it will allow them to reduce their prednisone dose and keep their lupus under control.

Q: When being treated with BENLYSTA infusions, will the patient have to stop other medications such as Plaquenil or prednisone?

A: No, the patient will not have to stop prednisone or Plaquenil. Hopefully, one can get the dose of prednisone down to a lower amount, but medications including immunosuppressives, steroids such as prednisone and Plaquenil can still be used concurrently.

Q: How long does the patient have to take BENLYSTA?

A: We do not know the answer to the length of time patients will be on BENLYSTA. Typically lupus flares up and is active for months, but sometimes years. It may be possible to treat the lupus patient during flares of the disease and then discontinue the medication after a few months, but it is uncertain about that period. In relatively few patients, it may be a lifelong therapy. Though we know about the clinical trials of BENLYSTA, we all need more experience in using this medication to develop recommendations on the length of use for most lupus patients.

Q: Do you think the company that manufactures BENLYSTA will ever be on a prescription assistance program?

A: I do believe that the company that makes BENLYSTA has taken this into account and is devising such a program. Details are still emerging. The LFAI can help with this question as the information becomes available. You can also check their website at www.benlysta.com.

Q: I am an SLE survivor since 1995. This [BENLYSTA] is great news. When will this medication be on the market?