First New Lupus Drug in 50 Years: Benlysta Gains FDA Approval

By Jane Langille | Posted April 18 2011

For the first time in over 50 years, the U.S. Food and Drug Administration (FDA) has approved a new drug for lupus, a breakthrough drug called Benlysta (belimumab).

Anca D. Askanase, MD, MPH was Principal Investigator at the New York University site for Benlysta research and also serves as a Member of the Lupus Foundation of America’s Medical-Scientific Advisory Council. Askanase says, “Benlysta is a major breakthrough for both doctors and patients. The FDA approval is an incredibly important victory.” Since the announcement in early March, she has already received many patient inquiries about Benlysta.

Lupus or SLE (systemic lupus erythematosus) is an autoimmune disorder that affects at least 1.5 million Americans and more than five million people worldwide. Lupus causes the body’s immune system to attack healthy tissue and organs. Symptoms can include inflammation of joints, nervous system or brain, debilitating pain, organ damage, skin rashes and fatigue. Lupus affects mostly women aged 15-44 and is three times more common among African-American women than Caucasian women.

As there is no cure, patients can only rely on treatments that help manage symptoms and slow the progression of the disease. Current standard therapies target the entire immune system, and include drugs classed as nonsteroidal anti-inflammatory drugs, corticosteroids, antimalarials or immunosuppressives. These treatments can lead to serious side effects including GI complications, osteoporosis, high blood pressure, diabetes, ulcers, cataracts or retina damage.

Benlysta is different because it is a monoclonal antibody that targets and blocks the activity of the BlyS protein, which is often found at elevated levels among patients with active lupus. According to Askanase, “a large percentage of lupus patients are antibody positive, so Benlysta should help a good majority.” The drug is...
administered by intravenous infusion over a period of an hour at 2-week intervals for the first three doses and then at 4-week intervals thereafter.

In two clinical studies, results at 52 weeks showed that patients who received Benlysta plus standard therapy experienced a statistically significant reduction in symptoms compared to control groups who received a placebo plus standard therapy. Test results suggested but did not definitively conclude that Benlysta may be able to reduce severe symptom flares and steroid doses. Askanase says, “It is premature to say that Benlysta will mean it’s possible to reduce standard therapy, but we’re hopeful.”

Benlysta is recommended for adult patients with active, autoantibody-positive SLE who are receiving standard therapy. It is not recommended for those with severe active lupus nephritis (involving kidney inflammation) or severe active central nervous system lupus. Common side effects noted in the clinical trials were: nausea, diarrhea, pyrexia, nasopharyngitis, bronchitis, insomnia, pain in extremity, depression, migraine and pharyngitis. Of note, in the clinical studies, African American patients and patients of African heritage did not appear to respond to Benlysta treatment, but additional studies will be conducted to evaluate further its safety and effectiveness for this subgroup of patients.

The FDA approval of Benlysta is a watershed achievement for lupus drug research. Benlysta is not only the first lupus drug to be approved by the FDA in over 50 years, it is the first drug that can specifically target and block BLyS autoimmune-antibodies.

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Visit the website for the Lupus Foundation of America (LFA) to learn more about lupus and to see videos about what the FDA approval of Benlysta means to researchers, doctors and patients. For more detailed drug information, visit sites for co-creators Human Genome Sciences and GlaxoSmithKline.