

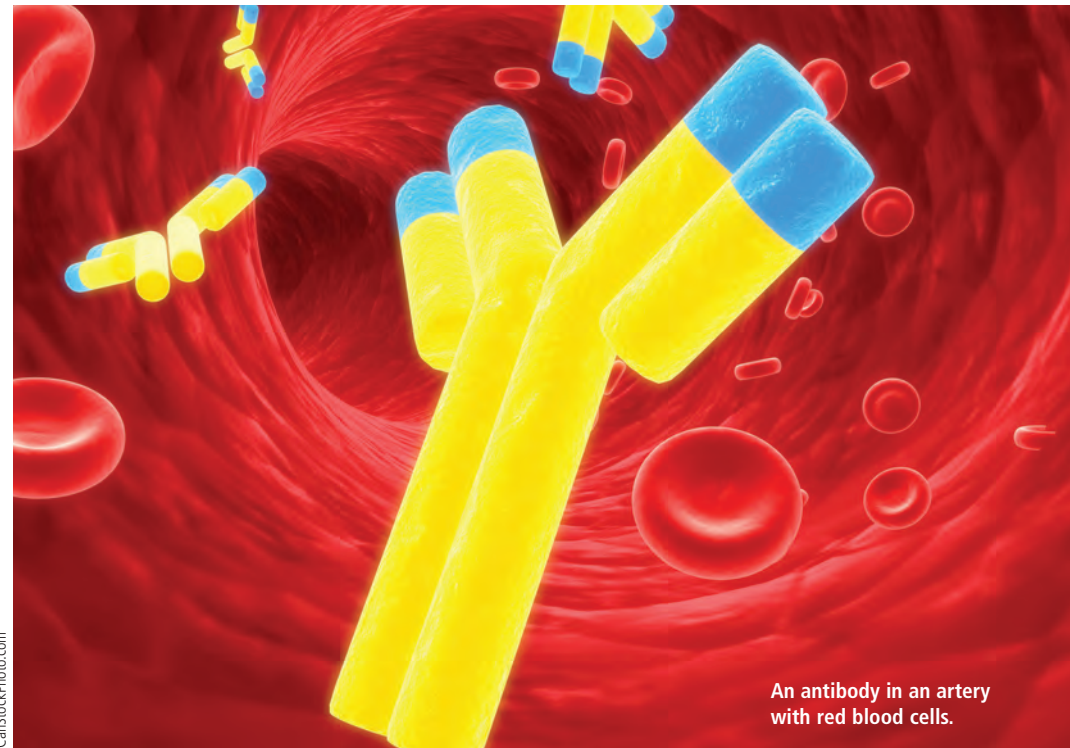


# LUPUS NEWS

## Belimumab By: Elena Massarotti, MD

**O**n March 9, 2011, the FDA approved belimumab (Benlysta), a new medication for treatment of lupus, based upon overall positive results from two large Phase III trials in over 1600 patients with active lupus symptoms. These studies were done in the United States, Europe, Latin America, and Asia. The patients enrolled in these studies were taking a wide range of different “background” medications to treat their lupus symptoms, including nonsteroidal anti-inflammatory drugs, corticosteroids, antimalarial medications (i.e. hydroxychloroquine or Plaquenil), as well as other immunosuppressive drugs like methotrexate or mycophenolate (Cellcept). This is the first FDA approved drug for the treatment of lupus since 1955.

**What is belimumab (Benlysta) and how does it work?** Belimumab is a biologic therapy—in other words, a therapy that is directed against a specific biological molecule involved in how lupus develops. Patients with lupus have increased levels of a molecule called B cell activating factor (BAFF). This factor is produced by B lymphocyte cells, and B cells are involved in producing the abnormal antibodies, such as anti-nuclear antibody and anti-double-stranded antibody, found in the blood of people with lupus. Belimumab is a *manufac-*



An antibody in an artery with red blood cells.

*tured* molecule that is directed against BAFF and acts by blocking the actions of BAFF. Blocking BAFF is thought to lead to the reduction in signs and symptoms of lupus. **How is it given?** This is given intravenously, once a month. During the first month of treatment, the medication is given every two weeks for the first three doses. At the Brigham and Women's Hospital, it will be given in the infusion center. It remains

unclear for how long this medication needs to be given in order to maintain treatment efficacy. The FDA-approved studies lasted one year. **For what aspects of lupus has belimumab been approved?** The studies upon which belimumab was approved enrolled patients with an established diagnosis of lupus and with active, ongoing symptoms of lupus, despite already taking something to treat *continued on page 2*

**Tip of the season** *By: Kathy McManus, MS, RD, Director Department of Nutrition, Brigham and Women's Hospital*



Eating whole grains in place of more refined grains is better for long-term good health. Whole grains can offer protection against diabetes and heart disease. To ensure that the food is truly a whole grain, on the Nutrition Facts label look for the word “whole” to be listed first in the ingredient list. You can also look for the Whole Grains Council “100% Whole Grain” stamp, which is now available on some products. Examples of whole grain food sources are: whole oats, whole wheat pasta, whole grain bread, barley, quinoa and brown basmati rice.

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**Linda T. Hiraki, MD, MS**

A Pediatric Rheumatologist pursuing a Doctor of Science degree in Epidemiology at the Harvard School of Public Health, Dr. Hiraki has received the Canadian Institute of Health Research Fellowship Award to support her research work. Working with Dr. Karen Costenbader, Dr. Hiraki has recently completed an analysis of the outcomes of pediatric lupus-associated end-stage renal disease patients, particularly the rates of kidney transplant and overall survival across race, ethnicity and the country. In another project, she is examining outcomes among pediatric systemic lupus erythematosus Medicaid enrolled patients.

Dr. Hiraki has a special interest in the genetics of complex rheumatologic diseases specifically of issues of heritability and risk prediction. Her doctoral dissertation work is investigating the genetics of vitamin D and the association with complex diseases including colorectal cancer and systemic lupus erythematosus.



**I-Cheng Ho, MD**

Dr. Ho is an associate professor of Harvard Medical School and a rheumatologist at Brigham and Women’s Hospital. He has received a Pilot Grant from Alliance for Lupus Research and a Research Award from the Department of Defense to study the function and clinical applications of *ets1*, a gene that is associated with lupus. This study will take advantage of the large lupus study population and the “BWH Lupus Biobank” and will investigate the role of this gene in lupus. He sees patients at the Arthritis Center of Brigham and Women’s Hospital at Boston and Brigham and Women’s/Mass General Health Care Center at Foxborough.



**Peter H. Schur, MD**

Dr. Schur is a Professor of Harvard Medical School and a Rheumatologist at Brigham and Women’s Hospital. He is the Director of the BWH Lupus Center, Emeritus. He is the former editor (1990-1995) of Arthritis and Rheumatism, the official medical journal of the American College of Rheumatology, and currently the Editor of UpToDate in Rheumatology, an online Medical Textbook available in virtually all teaching hospitals in the USA. He is the author or coauthor on over 300 papers on lupus and related matters published in peer reviewed medical journals and books. He is the coauthor, with the late Henrietta Aladjem, of “In Search of the Sun,” which they wrote as a guide for lupus patients. Dr. Schur sees patients Monday through Friday in the BWH Arthritis Center, attends on general medicine, and teaches medical students, medical residents, and rheumatology fellows. He and Dr. Ruth Ann Vleugels (Dermatology) direct a special Harvard Medical School course on lupus. Dr. Schur continues to direct the BWH Clinical Immunology Lab. He is currently doing research on cognitive abnormalities in patients with lupus as well as the role of autoantibodies to RNA in lupus.



ONGOING BWH LUPUS CENTER RESEARCH STUDIES

**Systemic Lupus Erythematosus Biobank:**

This biobank is collecting blood samples for future studies. The biobank will look at how and why lupus occurs in lupus patients. The biobank is seeking participants with lupus. The participants must be older than 18 and seen by a doctor in the BWH Arthritis Center. Participants will be asked to complete a questionnaire and give a blood sample. For more information please contact: Nicholas Nassikas at 617-732-6676 or email nnassikas@partners.org (IRB #: 2008-P-000130)

**Vitamin D3 in Lupus**

We are studying the possible benefits of vitamin D for lupus. To be eligible for this study, you must be at least 18 years of age or older and have a diagnosis of lupus. For more information, contact Jade at 617-732-5354 or e-mail at nhcumberbatch@partners.org (IRB #: 2008-P-002167)

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the symptoms. Belimumab was not directly compared with a single therapeutic agent, but was added on to standard therapy the patient was receiving at study entry. Patients who had been treated with rituximab at any time or intravenous cyclophosphamide for six months prior to study entry were not allowed to participate. A very small percentage of patients participating in the study had some kidney disease, but it was not characterized as severe. Most patients had involvement of the skin or joints. Patients with very severe kidney disease and very active disease affecting the brain or other parts of the central nervous system were excluded from these studies. The drug should not be given in patients who are receiving cyclophosphamide, or other biologic therapies (examples include rituximab, etanercept).

**What can lupus patients expect with treatment using belimumab?** The results from the trials showed that patients were able to reduce the dose of steroids they were taking, and that the number of flares was also reduced and that the amount of time to develop a flare was longer than in patients who were not treated with the drug. African American patients treated with belimumab in the trials did not appear to respond as well. The company that is selling belimumab, Human Genome Sciences (HGS), is planning a study to further examine the use of belimumab in African American patients, or patients with an African heritage.

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Welcome to our new column—"Ask the Expert!" In each newsletter, we will feature questions from patients. In this issue, Bonnie Bermas, MD, Director of the Lupus Center, answers your questions.

**Can you provide a list of foods to avoid?**

Often, patients will ask whether there are certain foods or medications to avoid if they have lupus. There is no "lupus diet" other than the more general recommendations of having a healthy and varied diet that includes lots of fruits and vegetables. There are no foods or supplements that have been definitely shown to cause lupus flares. We do recommend that persons with lupus limit their intake of saturated fats as in general lupus patients have an increased incidence of cardiovascular disease. For individuals with kidney disease they may be told to stay on a low salt and low protein diet.

**Do you recommend taking fish oil?**

Fish oil is a natural anti-inflammatory. This supplement therefore may have some benefit, in particular to those patients who have joint symptoms. So fish oil will not harm patients with lupus and in some patients they may feel better taking this supplement.

**Are there any risks for lupus patients using melatonin or should they avoid it altogether?**

There are some websites and information sources that claim that melatonin and echinacea will make lupus worse. However, there are no data to support these claims. Lupus patients may take melatonin and echinacea.

**Are lupus patients at higher risk for certain types of cancer and if so what should they do about it (i.e. increased screening, other precautions)?**

Lupus patients are at slightly higher risk for cancers. Whether this increased risk is due to medications is not clear. Higher rates of lymphomas, lung cancer, breast cancer and squamous cell cancer of the skin have been reported in lupus patients. While patients should not worry excessively about this risk, they should make certain to keep up to date with age appropriate cancer screening such as mammograms and colonoscopies. Finally, those patients who have co-existing Sjogren's syndrome are at even higher risk for lymphomas.

If you have questions you would like to have answered in next issue's "Ask the Expert," please email Dawn Peters at [cdp13@comcast.net](mailto:cdp13@comcast.net) and write "Ask the Expert" in the subject line.

**BWH Lupus Center Events – Past and Future**

**September 12th, 2010** – 18th Annual Lupus Walk on the Charles

Members of the BWH Lupus Center participated in the annual walk at the Richard T. Artesani Park, Brighton, MA.



**September 23rd, 2010** – Bone Health Talk

Guest speaker Sonali Desai MD, MPH gave a talk about ways you can take preventative measures against the development of osteoporosis.

BWH Lupus Center participants from left: Dr. Peter Schur, Dr. Bonnie Bermas, Vanessa DiMauro, Dr. Patricia Fraser, Kelley Keefe, Dawn Peters, Dr. Karen Costenbader.

**September 29th, 2010** – *Living with Lupus: Learn from the Experts*

Dr. Bonnie Bermas hosted the Lupus Foundation of America's *Living with Lupus: Learn from the Experts*, a conference call and online presentation for individuals living with lupus. This was part of the LFA's new quarterly education series, *Lupus: Learn from the Experts*.

**February 8th, 2011** – BWH Lupus Center Invited Guest and Visiting Professor

Mary Anne Dooley, MD, MPH gave a rheumatology grand rounds presentation entitled, "Treatment for Lupus Nephritis in the Coming Decade." She met individually with rheumatology fellows and staff and discussed two complicated cases of lupus nephritis at the noontime rheumatology outpatient teaching conference. Dr. Dooley is an Associate Professor of Medicine at the University of North Carolina, Chapel Hill, North Carolina. She is an active clinician in the UNC Thurston Arthritis Center and the UNC Kidney Center. She is an internationally-recognized expert in lupus kidney disease. Dr. Dooley's research interests lie in the area of clinical investigation and outcomes research in systemic lupus erythematosus, with publications focusing on environmental and hormonal risks and outcomes for lupus and lupus nephritis.

**April 9th, 2011** – *Living Healthy With Lupus: Family Planning, Pregnancy and Nutrition Tips for Women with Lupus*.

Talk held at 10am at the Boys and Girls Club, Yawkey Club of Roxbury. Lunch Provided. The speakers were Bonnie Bermas MD, Director of the BWH Lupus Center & Kathy McManus MS, RD, LDN, Director of the BWH Department of Nutrition.

**May 12th, 2011** at 5:30PM at The Dimock Center (55 Dimock Street, Roxbury, MA): *Living Healthy with Lupus: An Update on Lupus Care*. A talk by Dr. Elena Massarotti will be followed by a group discussion. Discussion participants will receive \$30 gift certificates. Please contact Nick Nassikas for more information by phone (617-732-6676) or by email ([nnassikas@partners.org](mailto:nnassikas@partners.org)).

**June 25-26th, 2011** – 7NEWS Partners HealthCare Health & Fitness Expo at the Hynes Convention Center. Please come and visit the BWH Lupus Center booth (#903).



## 2011 Calendar of Events from the Lupus Foundation New England

The Lupus Foundation of New England is an organization that helps people and families affected by lupus. It provides resources for education and support. It also helps to fund lupus research with other lupus organizations. ([www.lupusne.org](http://www.lupusne.org))

Monday, April 18, 2011 – 115th Boston Marathon

Thursday, June 9, 2011– Commitment to a Cure Cocktail Party, The Foundation Room at the House of Blues, Boston, MA

Saturday, September 10, 2011– 18th Annual Lupus Walk on the Charles, Richard T. Artesani Park, Brighton, MA

Wednesday, October 5, 2011– 3rd Annual Runway for a Cure, Crowne Plaza Hotel, Warwick, RI

Saturday, October 8, 2011 – 6th annual Jazz Club Event, Ryles Jazz Club, Cambridge, MA

November – 11th Annual Boston Lupus Pub Crawl, Bell in Hand, Boston, MA

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**What are the possible side effects?** All medications possess possible side effects. The FDA reported that data from the clinical trials showed that more deaths and serious infections occurred in the treatment groups compared those on background medications. (see link below) Live vaccines should not be given if a patient is taking belimumab—examples of live vaccines include the nasal influenza vaccine, oral polio vaccine, and the measles vaccine. The most common side effects in the studies included nausea, diarrhea, and fever. 1% of patients also experienced infusion reactions so pre-treatment with an antihistamine should be considered.

**Is belimumab right for me?** New medications offer hope for patients. There is great excitement in the medical community regarding belimumab, especially since there have not been any new drugs approved for lupus in over forty years. This drug represents a new way of treating the disease, and the available data to date shows that it is well tolerated. Whether it is right for you is a discussion you should have with your rheumatologist.

### FDA Notice of Approval:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm246489.htm>

**If you are interested in learning more about the lupus center or supporting our research and educational programs please call Erica Dumas (617) 525-8589 or visit our website [www.brighamandwomens.org/rheumatology/lupus/](http://www.brighamandwomens.org/rheumatology/lupus/)**

## LUPUSNEWS Spring 2011

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