

Alliance *for* Lupus Research

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SPECIAL REPORT



*Highlights from the*  
**American College  
of Rheumatology**  
*Meeting* Philadelphia, PA

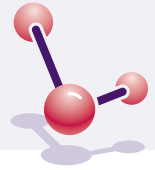
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# ACR

## SPECIAL REPORT

## Highlights of the American College of Rheumatology 2009 Scientific Meeting



Alliance for Lupus Research

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### CURRENT NEEDS IN AUTOIMMUNE DISEASE

Alliance for Lupus Research Scientific Advisory Board Chair Mary K. Crow, MD, delivered a major talk on progress into autoimmune diseases during the 2009 ACR meeting. While admitting that recent advances in drug development for rheumatic diseases make the area “one of the most interesting” in medicine, challenges remain, particularly in lupus, scleroderma and other areas. Specifically, she said, the field needs:

- A greater understanding of the underlying mechanisms of disease to guide the development of more effective therapies.
- To extrapolate information from studies of established therapies and use that information to guide the development of new drugs.
- Biomarkers and genetic fingerprints to help clinicians predict disease activity and determine when interventions are needed.
- Ways to balance control of disease with the toxicity of the intervention.

The highlight of the 2009 American College of Rheumatology (ACR) Annual Scientific Meeting in Philadelphia in late October was the positive results reported in two studies of the investigational drug, belimumab (Benlysta™). These findings were balanced, however, against more disappointing results from a pivotal clinical trial with rituximab (Rituxan®) that showed again that the drug provided no additional benefit to standard therapy in the population studied.

How could two drugs that have similar effects in the body have such different results? Alliance for Lupus Research (ALR) Scientific Advisory Board Chair Mary (Peggy) K. Crow, MD, thinks it may be related to the way the studies were designed.

“We have to look very carefully at the clinical trial data to determine why the rituximab studies did not meet its endpoints and the belimumab studies showed positive results,” she said. “What does this tell us about either clinical trial design or the mechanism of action of these two agents in the context of lupus? For instance, what did we learn about the role of B cell differentiation in the pathogenesis of lupus through these clinical trials? The answers will illuminate new directions for research.”

Dr. Crow was also struck by the number of studies presented on cardiovascular disease and pregnancy in lupus, both of which are covered in this report.

Dr. Crow attended the pre-conference meeting on basic science issues in lupus, primarily the genetics of the disease. “I think there has been continued progress since the publication of the ALR-funded International SLE Genetics Consortium (SLEGEN) that identifies additional genes that are gaining the statistical support needed to identify them with lupus,” she said. “However, there is growing agreement that investigators need to move to the next step and understand the functional implications of the genetic associations with the disease. In other words, exactly what do the associated genes do that contributes to lupus.”

Dr. Crow said she was intrigued by the potential of subphenotyping (i.e., identifying patients based on specific immunologic signatures, such as anti-DNA antibodies or interferon levels, and then linking those subtypes to specific genetic signatures).

“We’ve recognized that lupus is a very heterogeneous disease, but it is becoming clear from the data now that there are specific populations of patients,” Dr. Crow said. “This is particularly important when designing clinical studies to assess specific treatments. Some treatments may only be effective in patients with certain genetic profiles, a finding that is often difficult to obtain when all patients are simply classified as “lupus.” In other words, identifying different types of lupus may improve clinical trial results since many treatments appear to work differently in different patients.”

## The Latest Treatment Advances

There has not been a new drug approved for lupus in several decades. However, positive results from a major trial of the investigational compound belimumab (Benlysta™), announced during the ACR meeting, coupled with equally positive results of a second trial announced a week later, represent important milestones in the development of new therapeutic options for people with lupus. Human Genome Sciences, Inc. and its partner GlaxoSmithKline PLS are expected to submit marketing applications for regulatory approval of belimumab in the United States, Europe and other regions in the first half on 2010. If approved, belimumab will be the first in a new class of drugs called BlyS-specific inhibitors.

### Belimumab (Benlysta™)

Belimumab is a human monoclonal antibody that inhibits a protein necessary for the maturation of B-lymphocytes, cells involved in the autoimmune response that underlies lupus. Two recently announced Phase III trials showed that the drug significantly reduced disease activity and increased time to flare compared with placebo. In the first trial reported, participants also experienced less fatigue and improved quality of life, with no difference in adverse effects between those who received a placebo and those who received belimumab with the exception of infusion site reactions.<sup>i</sup>

Also reported during the conference were the results from a Phase II belimumab trial evaluating its efficacy and safety over four years in 449 people with lupus. Researchers found that the rate of adverse effects remained the same or declined over the four years, while the frequency of new flares decreased significantly. For instance, flares defined under the SLE Flare Index declined from 72% at six months to 16% after four years.<sup>ii</sup>

“Such results,” said presenter Michelle Petri, MD, professor of rheumatology at the Johns Hopkins Arthritis Center in Baltimore and a former ALR grantee, “show that the generic could be “widely used” as background therapy to reduce the use of steroids, improve quality of life and prevent flares. This could be the next generation of Plaquenil,” she said.

The ALR supported important basic and translational research on the molecule targeted by belimumab, a B-cell stimulator also known as BlyS. Research conducted by previously ALR-funded investigators William Stohl, MD, at the University of Southern California and Robert Carter, MD, currently the Deputy Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, established this molecule, BlyS, as a potential therapeutic target for people with lupus. Their research helped set the stage for this new clinical development program and trial. The ALR has funded more than five million dollars in B-cell research in the past ten years.

### Rituximab (Rituxan®)

There was more disappointing news for rituximab (Rituxan) and its potential role as a lupus therapy, however. Rituximab is a monoclonal antibody that depletes CD-20 B cells. Joan T. Merrill, MD, professor of medicine at the University of Oklahoma Health Sciences Center in Oklahoma City, presented data from two analyses of an ongoing trial evaluating rituximab in people with moderate-to severe lupus.

- In the phase II/III EXPLORER trial, participants were taking immunosuppressants and steroids. They received four infusions over six months of either a placebo or rituximab, during which the steroids were gradually stopped. After 78 weeks, the rate of serious and minor adverse events, including infection and infusion reactions, were similar between the two groups, although there was a higher incidence of viral herpes, neutropenia and serum sickness in the rituximab group.<sup>iii</sup>
- A study evaluating the subset of participants who showed a response to either placebo or rituximab found that severe and moderate flare rates were similar in both groups during the year they were followed. However, the average flare rate in the rituximab group was significantly lower than in the placebo group, suggesting that rituximab may increase the time to flare compared with placebo.<sup>iv</sup>

The results of the EXPLORER trial troubled clinicians, many of whom use rituximab for patients with lupus even though the drug has not been approved for that use yet. When asked how the results should be interpreted, Dr. Merrill replied: “while there is no evidence that rituximab works, I’m dissatisfied with the evidence that it doesn’t.”

And, in fact, other studies of the drug presented during the meeting show differing results.

- A study in 35 African-American and Hispanic patients who received four weekly infusions and were followed for two years showed a significant drop in disease activity throughout the study in all participants, even those with lupus nephritis.<sup>v</sup>
- A study in 86 people with lupus treated with rituximab with or without other lupus treatments for an average of 15 months found that an estimated 73% of treated patients showed improvement. Overall, 10 people had severe infections and one died from an infection.<sup>vi</sup>

**What this means for people with lupus?** It is quite likely that rituximab works in certain populations of people with lupus. The disappointing results from the large, manufacturer-sponsored clinical trials may be related to the way the trials were designed. The decision to use or not use rituximab is one you should make in conjunction with your doctor.

### Lenalidomide (Revlimid®)

Victoria P. Werth, MD, of the University of Pennsylvania School of Medicine presented results from an ACR-funded study showing that lenalidomide (Revlimid), a drug typically used to treat multiple myeloma and rare blood disorders called myelodysplastic syndromes, was also quite effective in treating severe cutaneous lupus in a small, preliminary study. Specifically:

- Four of the five patients in the study experienced a significant improvement.
- One of the four had to stop the drug because of new symptoms.
- The study identified biomarkers that could serve to assess patient response to the drug in future studies.<sup>vii</sup>

**What this means for people with lupus?** Lenalidomide may be an option for treating cutaneous lupus. However, much larger studies are required to assess its efficacy and safety.

## Biochemical Markers of Disease Activity

A major goal in lupus research is to find biomarkers – proteins, enzymes or other molecules – that could provide a “canary-in-the-minefield” early warning system of a lupus flare, enabling doctors to prophylactically treat patients and avoid the flare and the ensuing organ damage. Such biomarkers would also provide important information for clinical trials, evaluating the effect of treatment. This is an area in which the ALR has awarded millions of dollars in grants over the past few years.

Among this year’s reports:

### Interferon and Lupus

Two ALR grantees, Emily Baechler Gillespie, PhD, of the University of Minnesota, and Timothy W. Behrens, MD, currently with Genentech in San Francisco, were among the authors of a paper presented early in the conference validating the role of immune-system cells called interferon (IFN)-regulated chemokines as predictors of lupus flare.

## Lupus and Flu Vaccines: The Latest

One of the more timely presentations at the ALR conference focused on the impact of clinical and demographic features related to response to the influenza vaccine.

Because people with lupus have an increased risk of complications from the flu (regular flu or H1N1) due to immune defects and use of immunosuppressants, they should be vaccinated. But some studies find their immune system doesn't respond as well to the vaccine as that of people without lupus. There is also some evidence suggesting that the vaccine can stimulate new or increased autoantibody production, possibly triggering disease activity.

Sherry R. Crowe, PhD, of the Oklahoma Medical Research Foundation presented data showing that African-Americans with milder disease responded best to the vaccine, with Caucasians three times more likely to be poor responders. Poor responders were also more likely to be taking prednisone when they were vaccinated, to have hemolytic anemia and other blood disorders and to have more clinical signs of the disease.

However, the researchers found no difference in baseline autoantibodies between low and high responders, although low responders were more likely to have an autoantibody increase after receiving the vaccine while high responders were more likely to have a decline. Within the six weeks after vaccination, low responders were also more likely to have a flare.<sup>xi</sup>

**What this means for patients with lupus?** This study provides important information to help researchers conduct more studies to identify the best approach to giving flu vaccines in people with lupus to ensure the greatest immune response.

Previously, they reported on three chemokines identified in 373 patients who were followed for one year. In this study, they reported that the strongest link occurred with one of those proteins, IP-10, suggesting measuring levels of just that one molecule could help doctors predict upcoming flares.<sup>viii</sup>

Another presentation by ALR-grantee Mariana J. Kaplan, MD, of the University of Michigan in Ann Arbor demonstrated greater IFN activity in women with carotid plaque and overall lupus disease activity than in women without. They also showed that levels of circulating apoptotic endothelial cells might be another marker for blood vessel damage.<sup>ix</sup>

**What this means for people with lupus?** Measuring levels of these biomarkers in blood samples could enable doctors to predict future flares and begin treatment to prevent them, as well as identify women at greatest risk of cardiovascular disease.<sup>x</sup>

## Biomarkers for Lupus Nephritis

Canadian researchers presented a study conducted in 22 people with lupus nephritis undergoing a kidney biopsy. The researchers measured concentrations of four proteins in the participants' urine and then compared the protein levels to those in healthy people. When the researchers created a score for the four molecules, they found that patients with active lesions on their kidneys had a much higher increase in the score than patients with kidney scarring or chronic disease.<sup>x</sup>

**What this means for patients with lupus?** Tracking these four cytokines could enable doctors to evaluate and monitor kidney health in people with lupus nephritis instead of requiring a more invasive biopsy.

## Cardiovascular Disease and Lupus

People with lupus have a significantly increased risk of premature coronary heart disease (CHD) or atherosclerosis, stroke and other cardiovascular-related conditions than those without lupus. Some studies suggest risks of people with lupus are more than 50 times that of the general population.<sup>xii</sup> That is why it is so important to understand what underlies early

atherosclerosis in women with lupus so researchers can develop ways to prevent and treat the condition.

This focus was evident at this year's ACR conference, with numerous posters and oral presentations focused on cardiovascular disease in people with lupus. Among the presentations:

**Genetic link between lupus and stroke:** ALR-funded researcher Lindsay Criswell, MD, of the University of California, San Francisco and her colleagues presented the results of two studies demonstrating that genes thought to be associated with stroke and other clotting abnormalities (thrombosis) in people with lupus were also associated with the development of the disease itself.<sup>xiii</sup>

One study, the largest and most ethnically diverse analysis to date to evaluate novel genetic risk factors for thrombosis in people with lupus, strongly suggests that certain inherited changes in genes — along with other known risk

### Exercise and Pro-Inflammatory HDL

Women with lupus who rarely exercised were more likely to have pro-inflammatory HDL and atherosclerosis than women who were more active, regardless of disease severity. “The key to reducing that risk,” said lead author Elizabeth Volkmann, MD, of UCLA, “is strenuous activity that increases heart rate for at least 30 minutes a day, according to the study.”<sup>xvi</sup>

factors, such as the presence of antiphospholipid antibodies — help explain part of the increased risk of thrombosis in SLE patients.<sup>xiv</sup>

**What this means for people with lupus?** As researchers work to uncover the risk factors for developing blood clots in patients with lupus, genetic analyses could help them better predict which patients are at highest risk for this serious complication.

**HDL and atherosclerosis in lupus:** We are used to thinking of HDL cholesterol as the “good” cholesterol, the garbage truck of the blood vessels whose job it is to cart away the “bad” atherosclerotic LDL cholesterol to the liver for disposal and protect it from oxidation, the process that enables it to burrow into artery walls and begin the atherosclerotic process.

However, thanks to work by ALR-funded researchers and others, we now know that abnormal, pro-inflammatory HDL (piHDL) can exist in people with lupus and other autoimmune diseases, likely contributing to atherosclerosis.

In one study presented by Maureen A. McMahon, MD, of the University of California-Los Angeles, which also involved ALR grantees Bevra Hahn, MD, also of UCLA, and Michelle Petri, MD, of Johns Hopkins University, the researchers followed women with lupus who did not have cardiovascular disease and compared their plaque levels and piHDL presence to those of women without lupus. The goal was to see if piHDL cholesterol existed before the plaque or was related to the plaque itself. Overall, researchers found that:

- Women who had piHDL at the beginning of the study had a 24-fold increased risk of developing plaque or having existing plaque get worse compared to women with normal HDL.
- Older age, diabetes, and initial presence of plaque also increased the risk of progressing plaque, but to a much lower degree than piHDL.
- The presence of piHDL remained stable over time, suggesting that it was not triggered by the plaque, but existed before plaque development.<sup>xv</sup>

**What this means for people with lupus?** The presence of piHDL may serve as a marker to identify women with lupus who have the highest risk of cardiovascular disease so more intense preventive steps can be initiated.

**Peeking at Blood Vessel Walls:** ALR-grantee Paolo C. Colombo, MD, of Columbia University College of Physicians and Surgeons, described a new, minimally invasive, safe method to sample and study the endothelium, the inner layer of blood vessels that plays a key role in atherosclerosis. The new method Dr. Colombo and his colleagues describe can help researchers find lupus-specific processes that begin, sustain and possibly, end inflammation and atherosclerosis in people with lupus.<sup>xvii</sup>

**What it means for people with lupus?** The information learned by studying the endothelium could lead to new methods of preventing and treating early atherosclerosis in people with lupus.

## Lupus Nephritis

Lupus nephritis occurs in most patients with systemic lupus erythematosus (SLE). The disease typically presents within the first two years after SLE diagnosis, with nearly half of all patients developing it in the first year.<sup>xviii</sup> Overall, an estimated 5 to 20 percent of patients, even those who receive appropriate treatment, develop end-stage renal disease requiring dialysis or transplant within 10 years of diagnosis.<sup>xix, xx, xxi</sup> Thus, identifying biomarkers that predict damage or nephritis flares as well as the best possible treatment to prevent long-term damage are critical research focuses in this area.

Some of the more relevant studies for people with lupus nephritis and the doctors who treat them include:

- **Blood levels of mycophenolate mofetil (MMF):** A study evaluating blood levels of MMF in patients with active and inactive lupus activity found a tenfold difference among patients in terms of the amount of the drug they received. This suggests that clinicians are not clear on exactly how much MMF is most beneficial.

To determine the link between dosage and efficacy, French researchers measured blood levels of MMF in lupus nephritis patients and compared them to the level of disease in the patients. The higher the blood level (indicating a higher dosage), the more likely participants were to have inactive disease.

Researchers identified a drug threshold of 35 mcg.h/ml as an appropriate target for MMF dosing to reduce the likelihood of disease activity. Their results also hinted that African-Americans, who tend to develop lupus nephritis earlier and have more severe lupus nephritis than Caucasians, may require even higher dosages.

“The message for physicians,” said presenter Laurent Arnaud, MD, during his presentation, “is to increase the MMF dosage as high as possible before encountering toxicities.”<sup>xxii</sup>

**What this means for people with renal nephritis?** If your doctor has had you on MMF for your disease and you continue to have active disease, the dosage may not be high enough. You should talk to your doctor about what is the best dosage for you.

- **Mycophenolate mofetil vs. azathioprine in maintenance therapy:** The MAINTAIN (Mycophenolate Mofetil versus Azathioprine for Maintenance Therapy of Lupus Nephritis) trial compared MMF to azathioprine (AZA) for maintenance therapy in people with proliferative lupus nephritis.

**Bottom line?** Both worked equally well with similar side effects, although those in the AZA group had slightly more blood-related side effects.<sup>xxiii</sup> “One major issue with MMF,” noted the lead investigator Frédéric A. Houssiau, MD, PhD, of the Universite Catholique Louvain in Brussels, Belgium, “is that women who plan to become pregnant need to stop taking the therapy before they conceive given serious risks of birth defects.”

What this means for people with lupus? Either MMF or AZA is appropriate for preventing lupus nephritis flares.

- **Rituximab and lupus nephritis.** Despite some small, uncontrolled clinical trials suggesting that rituximab (Rituxan<sup>®</sup>) may work for people with lupus nephritis, a study comparing its use in addition to MMF found no benefit overall.

However, additional analysis of the results revealed that African-American patients were more likely to respond to rituximab than Caucasian patients. In addition, eight patients who received placebo had to be “rescued” with cyclophosphamide compared to just one patient who received rituximab.

The study also showed that the rituximab participants had lower levels of anti-DNA antibodies and complement, indicators of disease activity, regardless of their response to the drug. What that means in terms of the disease itself, however, isn’t clear.<sup>xxiv</sup>

**What this means for people with lupus?** Rituximab may not have a place as therapy for lupus nephritis, although more studies in different populations are needed.

## Pregnancy and Lupus

Women with lupus who become pregnant have a much higher risk of pregnancy-related complications, miscarriage, and premature delivery than women without the disease. Infants may also be born with neonatal lupus, a normally benign condition that typically disappears within a few weeks. In about 2 percent of babies, however, the condition causes fetal heart block, a potentially fatal, abnormal heart rhythm that requires a permanent pacemaker.

Because lupus primarily strikes women of reproductive age, identifying ways to predict which women and infants will have increased risks of complications has become a research priority.

Several presentations at the ACR meeting attested to the progress being made in this area. Specifically:

**Markers for pregnancy complications:** An analysis of the condition of 177 women involved in 406 pregnancies before and after their lupus diagnosis found that:<sup>xxv</sup>

- Women with proliferative lupus nephritis had a higher risk of preeclampsia.
- Women with hemolytic anemia (a condition in which not enough red blood cells are made in the body) had a higher risk for preterm delivery and preeclampsia.
- Women with Raynaud's phenomenon had a higher risk for preterm delivery.
- Women with antiphospholipid syndrome (a blood disorder that causes abnormal clotting) had a higher risk of miscarriages, especially in the second trimester, slow fetal growth, and preeclampsia.
- Women who got pregnant less than six months after a flare were at higher risk of preeclampsia.

**What this means for women with lupus?** Plan your pregnancy to begin at least six months after your last flare and make sure your doctors are aware that lupus nephritis, hemolytic anemia and antiphospholipid syndrome all increases your risk of complications.

- **Preventing congenital heart block:** The long-awaited results of a trial designed to evaluate whether giving pregnant women intravenous immunoglobulin could prevent congenital heart block in their babies found no benefit to the therapy. However, the researchers noted, the therapy was safe and, because they used very low doses, the lack of efficacy may be related to the amount of medication the women received. This study involved ALR-funded researcher, Jill P. Buyon, MD, of New York University School of Medicine.
- **Preventing vascular complications in pregnancy:** One reason for the high rates of preeclampsia and low birth weight babies in pregnant women with lupus is related to an inadequate blood supply to the placenta. Thus, the fetus doesn't get enough nourishment and fails to grow.

Researchers, including ALR-funded scientists Jane E. Salmon, MD, of Weill Cornell Medical College, Jill P. Buyon, MD, of New York University School of Medicine, and Michelle Petri, MD, of Johns Hopkins University in Baltimore, studied 23 women with lupus who had poor outcomes in their pregnancy, 100 women with lupus who had healthy pregnancies and 98 pregnant women without lupus.

The researchers found much higher blood levels of the molecules SFit-1 and sEng, which prevent blood vessel development, in women with poor pregnancy outcomes than in women with lupus who had healthy pregnancies or in women without lupus.

What this means for women with lupus? Once we understand more about the mechanism behind the increase in these blood factors, we can begin to identify therapy to reduce levels.

- **Predicting neonatal lupus and its severity:** In one form of neonatal lupus, a rash appears on the baby then disappears a few months later. A study presented at the ACR meeting demonstrated that a rash in one child predicted the presence of neonatal lupus in future siblings.<sup>xxvii</sup>

Another study also found a higher risk of neonatal lupus in siblings of a child affected with neonatal lupus. However, if the first child didn't have a rash or heart block, there was little to no risk that future siblings would develop heart block. However if the original child had heart block, there was a 15.4% risk that its siblings would also have heart block.

Finally, a third study found significantly elevated levels of enzymes called membrane-type matrix metalloproteinase-2 (MMP-2) in the cord blood of babies who developed cardiac neonatal lupus compared to those who didn't.<sup>xxx</sup>

**What this means for women with lupus?** Women who had a previous child with any form of lupus nephritis should be carefully followed during subsequent pregnancies. They should also be considered for studies evaluating preventive approaches for neonatal lupus. In addition, cord blood levels of MMP-2 may one day be used to predict which babies with neonatal lupus will go on to develop heart problems.

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More information about lupus and treatment advances can be found by visiting [www.lupusresearch.org](http://www.lupusresearch.org).

*The 2009 American College of Rheumatology Meeting Special Report* was made possible in part by generous support from Biogen Idec, Genentech and Johnson & Johnson.



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