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ALTERNATIVE THERAPY FOR LUPUS NEPHRITIS

Mycophenolate Mofetil May Be More Effective in Certain Patients

Washington, DC (Friday, April 10, 2009) —Lupus is a rare but serious disease that mainly affects women of child-bearing age and occurs when the body's immune system goes awry, damaging a variety of organs. When kidneys are targeted, patients develop lupus nephritis, which can result in kidney failure and death. Lupus nephritis is often treated with the cancer drug cyclophosphamide, which suppresses the immune system but also causes hair loss, nausea, vomiting, and infertility.

The immunosuppressant drug mycophenolate mofetil is less commonly used than cyclophosphamide, but may be an attractive alternative for some patients, according to a study appearing in the May 2009 issue of the *Journal of the American Society of Nephrology* (JASN).

Recent studies have suggested that oral mycophenolate mofetil (commonly used to prevent graft rejection after organ transplants), may offer advantages over intravenous cyclophosphamide. To test this hypothesis, Neil Solomons, MD (Aspreva Pharmaceuticals Corporation, Canada), and other researchers designed one of the largest, most racially diverse trials ever conducted in lupus nephritis patients. The researchers recruited 370 patients from 88 centers in 20 countries; patients received either cyclophosphamide or mycophenolate mofetil for 24 weeks.

By the end of the treatment schedule, the investigators did not detect a significantly different response rate between the two groups of patients: 104 out of 185 (56.2%) patients responded to mycophenolate mofetil compared with 98 out of 185 (53.0%) to cyclophosphamide. There were nine deaths in the mycophenolate mofetil group and five in the cyclophosphamide group, but there was no significant difference between the groups with respect to the rates of adverse events.

Both treatments are likely to improve lupus nephritis patients' health and one therapy cannot be deemed superior to the other. However, researchers noted important differences across racial and ethnic groups, with more high-risk, non-Caucasian, non-Asian patients responding better to mycophenolate

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mofetil than to cyclophosphamide. Also, some lupus nephritis patients may prefer mycophenolate mofetil therapy since it does not affect fertility.

The study's data "will allow clinicians to gain a unique insight into the efficacy and safety of these commonly used therapies in the treatment of renal and non-renal lupus in a racially diverse population," said Ellen Ginzler, MD (SUNY–Downstate Medical Center), the principal US investigator for the ALMS study group.

This study was sponsored by the Aspreva Pharmaceuticals Corporation as part of the Roche-Aspreva collaboration agreement. At the beginning of 2008, the Aspreva Pharmaceuticals Corporation was taken over by the Galenica Group and operates since then under the name Vifor Pharma. Co-Authors include Ellen Ginzler, MD, Gerald Appel, MD, Mary Anne Dooley, MD, David Jayne, MD, David Isenberg, MD, David Wofsy, MD, Eduardo Mysler, MD, Jorge Sanchez, MD, Gabriel Contreras, MD, and Lei-Shi Li, MD. Dr. Appel has received honoraria (for lecturing) from Vifor Pharma, served as a consultant for Vifor Pharma, and received grants for ALMS. Dr. Contreras has received honoraria for travelling and lecturing from Roche. Dr. Dooley has served as a consultant for Teva and Vifor Pharma; received honoraria from Vifor Pharma; provided expert testimony for UCB; and received grants from Bristol-Myers Squibb, Vifor Pharma, Amgen, and Roche; Dr. Ginzler has received honoraria and grants from Vifor Pharma. Dr. Jayne has received grants from Vifor Pharma. Dr. Solomons is an employee of Vifor Pharma. Drs. Isenberg, Li, Mysler, Sanchez-Guerrero, and Wofsy have nothing to declare.

The article, entitled "Mycophenolate Mofetil *versus* Cyclophosphamide for Induction Treatment of Lupus Nephritis," will appear online at <http://jasn.asnjournals.org/> on April 15, 2009, doi 10.1681/ASN.2008101028.

Founded in 1966, the American Society of Nephrology (ASN) is the world's largest professional society devoted to the study of kidney disease. Comprised of 11,000 physicians and scientists, ASN continues to promote expert patient care, to advance medical research, and to educate the renal community. ASN also informs policymakers about issues of importance to kidney doctors and their patients. ASN funds research, and through its world-renowned meetings and first-class publications, disseminates information and educational tools that empower physicians.

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