

LUPUS RESEARCH ALLIANCE

FORMERLY



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Lupus Research Alliance Welcomes Voclosporin Trial Results

First Promising Phase II Data in Lupus Nephritis

The Lupus Research Alliance congratulates Aurinia Pharmaceuticals on achieving the first positive Phase II study of a greatly needed potential treatment for lupus nephritis.

Up to 60% of people with lupus develop lupus nephritis, a devastating complication that can cause kidney failure and even death. Lupus nephritis is usually treated with heavy doses of steroids and, in most cases, additional potent drugs that suppress the immune system. People with lupus nephritis are at high risk for heart and blood vessel damage.

Top-line results from the landmark [AURA-LV trial](#) reported that compared with patients receiving only standard-of-care treatment with immunosuppressants and steroids, those who also received the investigational drug voclosporin were twice as likely to achieve complete remission. Safety issues, however, raised concerns with 13 deaths reported. Aurinia spokespeople noted that a disproportionate number of deaths occurred in Asia and hypothesized that this disparity may be explained by several factors including patient management and exposure to infections, as well as the severity of disease in this patient population. Further data analysis is expected to confirm whether adverse effects were related to the drug or to the disease itself.

“Maintaining consistency among clinical trial centers throughout the world, particularly in remote areas with varying access to healthcare, has long plagued research studies in lupus and other diseases,” commented Lupus Research Alliance Co-CEO Kenneth M. Farber. “That’s one reason the Lupus Research Alliance recently established the Lupus Clinical Investigators Network (LuCIN) of 60 top academic centers in the U.S. and Canada. Conducting trials in investigative sites that have been fully evaluated and approved for lupus trials helps assure that all patients in a study receive comparable care.”

“We welcome the AURA-LV results with optimism tempered by caution,” noted Margaret G. Dowd, Co-CEO of Lupus Research Alliance. “The magnitude of benefit is quite striking and unprecedented in lupus nephritis, but the number of deaths is a concern that must be taken seriously. We are very hopeful that further analysis of the safety data will confirm that voclosporin can provide a safe and effective treatment for this devastating disease. Meanwhile, by demonstrating the importance of a critical pathway in lupus, this trial has already made a significant contribution toward future drug development.”

The immunosuppressant voclosporin is a novel drug that aims to inhibit or block calcineurin, a protein that activates T cells – key players in regulating the immune system. In lupus, the immune system, which is designed to protect against infection, creates antibodies that attack the body's own tissues and organs -- the brain, heart, lungs, blood, skin, joints and, most commonly, the kidneys.

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