



**New Study Sheds Light on the Challenges of Developing
Lupus Treatments**

*Lupus Foundation of America Funded Research First to Use Pooled Data from Previous
Treatment Trials*

(November 7, 2011, Washington, DC) **LFA-** Initial findings from a research study funded by the Lupus Foundation of America (LFA), the first-ever to use pooled data from five industry-sponsored treatment trials, will be presented during the annual scientific meeting of the American College of Rheumatology being held in Chicago, November 7-10, 2011. The study examines the effect of background medications taken by individuals enrolled in these clinical trials. This study is the first in a series of studies, and part of an overall initiative spearheaded by the LFA, that involves stakeholders from industry and key lupus opinion leaders to seek insights and trends from previous trials in an effort to improve the design of future lupus clinical trials. Due to the complexity of lupus, there is an urgent need for an arsenal of safe, effective, and tolerable treatments for lupus.

During a clinical trial, individual participants are on potent background medications, such as corticosteroids, chemotherapies, and antimalarials that may have toxic and disabling side effects, including bone loss and osteoporosis leading to joint replacements, loss of fertility, cardiovascular complications, and more. It is believed that these medications may have minimized or masked the impact of the investigational therapy in many recent lupus clinical trials.

Initial reports from the pooled data show that individuals enrolled in a standard of care treatment group during the clinical trials had a high response rate (38 percent to 52 percent over a 52-week period). High response rates for people receiving the standard of care treatments may explain the difficulty in demonstrating the efficacy of the investigational therapy over the standard of care medication.

“The LFA’s early findings are part of an ongoing effort to gather and analyze lupus clinical trial data,” said Kenneth C. Kalunian M.D., chair of the LFA data mining initiative and Associate Professor of Medicine, University of California at San Diego. “This study and future projects will include analyses on the effects of steroid dosing and patient demographics on response rates. These projects may provide needed insight on patient response and help create pathways forward for the development of new treatments.”

Potent background medications taken by individuals enrolled in clinical trials represent only one of a number of barriers that have slowed the development of new treatments for lupus. Others include: the unique biology and heterogeneity of the disease; the lack of a clearly defined pathway for measuring outcomes in lupus clinical trials; and the complexity of instruments used by investigators to assess disease activity.

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