



Lupus Foundation of America Achieves International Consensus on Definition of a Lupus Flare

LFA-FLARE Definition Will Make Significant Contribution to Lupus Clinical Research

(Washington, DC-- January 10, 2011) The [Lupus Foundation of America](#) (LFA) spearheaded a four-year worldwide initiative with more than 120 lupus experts from 11 countries, the pharmaceutical and biotechnology industries, and federal agencies, which resulted in the first-ever global definition of a lupus flare. The development of *Lupus Foundation of America Flare Definition (LFA-Flare)* helps to overcome long-standing barriers to the development of new, safe, and more tolerable treatments for lupus.

For the past 15 years, many trials of new investigational medicines for lupus have failed to show significant benefits for patients. A consistent and meaningful definition for a lupus flare is critical to evaluating the effectiveness of treatment over time. The new definition will enable more precise outcome measures for future studies, such as the number of flares or the time between flares. This will have a positive impact on the quality and scientific basis of clinical trials, which are required by the U.S. Food and Drug Administration (FDA) to demonstrate the effectiveness of any new therapy before it can be approved for general use in patients.

The consensus definition is: *A flare is a measurable increase in disease activity in one or more organ systems involving new or worse clinical signs and symptoms and/or lab measurements. It must be considered clinically significant by the assessor and usually there would be at least consideration of a change or an increase in treatment.*

“This definition addresses several controversial issues about how we look at flares of disease, which may have been interfering with the accuracy of how we evaluate new treatments,” said Joan T. Merrill, M.D., head of the Clinical Pharmacology Research Program, Oklahoma Medical Research Foundation, and LFA Medical Director.

A paper describing the definition and the consensus process is now available online and will be published in the March or April issue of the medical journal [LUPUS](#). LFA-FLARE has high face validity and now is ready for validation in clinical studies. The Systemic Lupus International Collaborating Clinics (SLICC), a leading international consortium of lupus doctors, is evaluating this definition as a basis for modified outcome measurements of flare to provide an improved scientific basis for clinical trials.

The LFA thanks the lupus researchers from universities and industry who contributed their expertise to this project. A worldwide effort such as this brings hope to millions of people around the world who are living with lupus that new medicines are on the horizon.