



DISCOVERY

Transforming lives through innovation.



October 7, 2014

Dear Friends,

We are writing to share the news that Eli Lilly announced plans to discontinue their development of tabalumab as an investigative lupus treatment based on results of two Phase 3 clinical trials.

While this setback is disappointing, we at the [Lupus Research Institute \(LRI\)](#) urge the community not to be overly discouraged. Past experience tells us that failure in a trial does not necessarily mean that the drug will not benefit lupus patients. Cellcept® (mycophenolate mofetil) and Rituxan® (rituximab) for example, both failed in lupus trials but are widely used to treat lupus patients because they are approved for other indications and evidence of their safety and efficacy exists. The same situation could unfold with tabalumab.

Dr. Richard Furie, Chief, Division of Rheumatology and Allergy-Clinical Immunology, North Shore-LIJ Health System and industry consultant noted, “Although we don’t like seeing negative results in SLE clinical trials research, failed trials have taught us a lot. Additional analyses of the clinical and biologic data are needed before rendering a final opinion. The fact that the high dose in one of the two studies was effective supports the BLyS (BAFF) pathway as a relevant pathway in SLE. The information gleaned from these trials will help us advance the field.”

Need to Support and Foster Innovation

Data and insights from the tabalumab trials will inform development of new approaches to lupus clinical trials – innovation that is sorely needed as these trials show. We need new outcome measures – tools to evaluate when a therapy is working – as well as new approaches to trial design. And we need the biomarkers to identify patients most likely to benefit from a particular experimental drug.

All Hands on Deck

No single company or group can address these issues alone. That’s why the LRI is driving collaboration among patients and families, pharmaceutical and biotechnology companies, scientists and government to catalyze research innovation. The LRI’s Industry Council is such a catalyst with 14 leading pharmaceutical and biotechnology companies working together for the first time to solve the common issues all face in lupus drug development.

On behalf of the lupus community, we thank Lilly for undertaking this tremendous effort and for

the learnings researchers will take away. To the patients who took part in the tabalumab trials we owe our greatest appreciation. Their contribution is not in vain. Rather, their participation was essential to providing the information that will move us toward success in other trials for better treatments.

There is great strength in the lupus community with collaboration among its members, great progress in the novel research discoveries of the past decade, and great promise with the many investigational treatments now in development.

[Full Press Release from Lilly](#)



Margaret G. Dowd
President and CEO, Lupus Research Institute

About the Lupus Research Institute

The world's leading private supporter of innovative research in lupus, the LRI champions scientific risk-taking in the hunt for solutions to this complex and dangerous autoimmune disease.

Lupus Research Institute
330 Seventh Avenue, Suite 1701, New York, NY 10001
T: 212.812.9881 F: 212.545.1843
e-mail: Lupus@LupusNY.org

LupusResearchInstitute.org | [Privacy Policy](#) | [Email Preferences](#)