

# Lupus Therapeutics Shifting the Paradigm

The **Lupus Research Alliance** (LRA)—going bold and thinking big—has once again shifted the status quo of lupus research by becoming the first and only lupus organization to conduct its own clinical trials.

How did we achieve what once seemed unobtainable? We created Lupus Therapeutics (an LRA affiliated organization) and since the program started in 2017, remarkable progress has been made with 10 clinical trial currently underway.

*"Lupus Therapeutics serves as the organization that oversees the Lupus Clinical Investigators Network (LuCIN) we created with the LRA," said **Albert Roy**, Executive Director of Lupus Therapeutics. "We're on a mission to accelerate drug discovery for all people living with lupus." The program has had enormous success right out of the gate.*

*"When we started, about 30% of our sites participated in LuCIN trials. Today, all 57 sites participate—and many are conducting more than one trial," said Mr. Roy.*

Mr. Roy sees a direct correlation between the partnerships the LRA forged with the biopharma industry and the increasing number of trials now in our portfolio.

Attracting pharmaceutical companies to Lupus Therapeutics was no easy undertaking. The industry is highly focused on conducting trials in very specific ways. *"It took some convincing to get pharma to buy into the idea that working together through our LuCIN network could be mutually beneficial," said Mr. Roy.*

But over time the LRA proved that our network was turnkey—ready to go with: Sites located among the most reputable academic medical institutions in the world ... top-flight investigators ... and a lupus patient population that shows interest in participating in clinical trials.

*"The extraordinary level of research being conducted at these centers means being better able to collect critical data. Pharma now understands this concept and accepts the idea that our expertise offers leverage in generating a deeper understanding of lupus down*

*to the molecular level," explained Mr. Roy.*

The result: Lupus Therapeutics has forged strategic partnerships with nine different pharmaceutical companies. And today, it is moving forward on a wide range of scientific investigations—from a smartphone app to relay lupus symptom information in real time ...

to evaluation of delayed-released Prednisone ... to an innovative imaging procedure to assess lupus nephritis.

In summing up Lupus Therapeutics' advances, Mr. Roy points out the pivotal role played by the LRA:

*"Quite simply, none of our achievements would have been possible without the LRA. The organization's credibility with leading lupus investigators has enabled Lupus Therapeutics to quickly build working relationships around clinical trials. At the end of the day we are a patient advocacy organization—where people living with lupus are always front and center."*



*Albert Roy*

For more information about the way **Lupus Therapeutics** works, please take a look at our page 2 article on the progress we are making in encouraging patients to participate in lupus clinical trials.

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## 10 LUPUS THERAPEUTICS STUDIES CURRENTLY UNDERWAY

### TAK-079

*A Study to Evaluate the Safety of TAK-079*

### PAISLEY-SLE

*A Phase II study to evaluate a novel, oral therapy in SLE*

### ORKIDS

*A study to evaluate the effects of krill oil in SLE*

### LOTUS

*A Phase III study to evaluate Stelara® in SLE*

### DIVINE

*A study to evaluate a novel imaging procedure to access Lupus Nephritis (LN)*

### VALUE

*A study to evaluate electronic/mobile based patient reported outcomes*

### RIFLE

*A study to evaluate delayed-released Prednisone*

### IBERDOMIDE–

*A Phase II study to evaluate a novel, small-molecule therapy*

### BMS-986165

*An investigational study to evaluate BMS-986165 for Lupus Nephritis*

### EVOBRUTINIB

*A Phase II study to evaluate a novel inhibitor in SLE*

For more information, please visit [lupusresearch.org](http://lupusresearch.org)

## Peer-to-Peer Involvement Advances Scientific Exploration

Many dynamics of lupus contribute to the fact that its complexities have eluded the scientific community—but new hope may come from patients themselves.

This is why Lupus Therapeutics piloted the **Patient Advocates for Lupus Studies (PALS)** program in the Summer of 2019. PALS focuses on reaching diverse populations to improve their knowledge and awareness of trials, and to promote enrollment by people living with lupus.

*“Under-enrollment in lupus trials is critical because of the heterogeneity of the disease. There is no one test to evaluate activity per se—and symptoms that effect patients most, like severe fatigue at a level that disrupts daily life, aren’t yet measurable in a standardized, scientific way,”* said **Caroline Donovan**, Manager of Patient Engagement.

The new program, now in progress at five sites, is designed to engage people with lupus in various stages of clinical research ... increase enrollment ... and level the playing field for at risk populations.

Our basic premise is that individuals will be more likely to participate when they learn about clinical trials from a peer.

*“The goal is to strengthen the educational foundation about clinical trials without outright asking people to participate. Rather, peers they identify with can explain why he or she participated, what their experience was like, and why their participation was and is so critical,”* said Ms. Donovan. *“When it begins with two people talking about a shared experience, it makes participation in a trial less scary.”*

This important initiative has tremendous potential to advance the mission of Lupus Therapeutics and address cultural inequities in health care. That’s why nine of eleven advocates are African American.



*Caroline Donovan*

*“I’m looking forward to easing patients’ fears about clinical trials and on how the trial may/may not affect them...so that when they make the decision to participate or not, it’s from an informed position and not fear/uncertainty.” – a PAL*

## FACES OF LUPUS

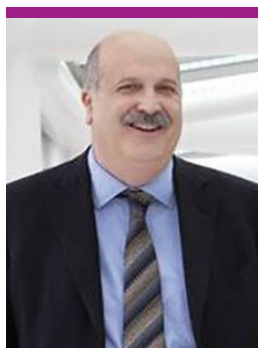
# Welcoming Daniel J. Wallace, MD To Lupus Therapeutics

The Lupus Research Alliance (LRA) affiliate Lupus Therapeutics is pleased to announce that **Daniel J. Wallace, MD** joins as a new member of its distinguished Board of Directors.

A renowned leader in clinical research and care for lupus and other rheumatologic diseases, Dr. Wallace is Medical Director of the Wallace Rheumatic Study Center and Associate Director of the Rheumatology Fellowship Program at Cedars-Sinai in Los Angeles. With over 40 years of experience, his office manages the care of 1,500 people with lupus, the largest practice of its kind in the United States.

Over his illustrious career, Dr. Wallace has been involved in more than 50 pivotal clinical trials for lupus and is currently conducting six trials. He has published 430 papers in peer-reviewed journals and contributed chapters to nearly 30 books and supplements. His own eight books, three of which are widely accepted authoritative works on lupus including the best known—Dubois Lupus Erythematosus, now in its 9th edition.

*“Clinical trials must be designed with the views and needs of real patients in mind. And there is no one with more expertise in treating people with lupus or in planning and conducting clinical trials than Dan Wallace,”* said **Albert Roy**, Lupus Therapeutics Executive Director.



*Daniel J. Wallace, MD*

## Lupus Therapeutics Board of Directors:

**Kelly McVearry**, PhD, MA, Ed.M. has two decades of experience leading the design, development, due diligence and commercialization of life science and information technologies.

**William J. Wolfe**, Co-founder, Chairman and CEO of First Washington Realty, Inc., a privately held real estate investment advisory firm specializing in ownership of neighborhood and community shopping centers in major metropolitan areas.

**Brian Kotzin**, MD has been committed to patient care, research, and teaching during his 25-year academic career.

**Joseph Mauriello**, Former Deputy Chairman & COO of KPMG, after 40 years of leadership positions.

**Jennie DeScherer**, is an active Board member of the Lupus Research Alliance having helped lead its predecessor organizations – S.L.E. Lupus Foundation (S.L.E.) and the Lupus Research Institute (LRI) – since their early years.

**Alexander von Perfall**, joined Royalty Pharma in 2009 as Vice President, Investor Relations & Public Affairs.

**Cantey Boyd**, serves as a Managing Director of Baker Brothers Investments, a fund management company focused on long-term investments in life-sciences companies.

**Daniel J. Wallace**, MD, FACP, MACR (see above).

**Kenneth M. Farber**, serves as the President and CEO of the Lupus Research Alliance.

**Albert Roy**, serves as the Executive Director of Lupus Therapeutics.

## POTENTIAL NEW TREATMENT IN PHASE III TRIAL

The Lupus Research Alliance is excited to announce that a potential new medicine for lupus—anifrolumab—reduced disease activity versus placebo in a second Phase III study.

Anifrolumab is a therapeutic antibody that blocks type I interferons, a molecule that promotes lupus inflammation.

The LRA was ahead of the curve by funding more than 15 studies that investigated type 1 interferons over the past decade. These studies were pivotal to the eventual development of anifrolumab.

Called TULIP 2, the one-year pivotal trial measured disease activity using a well-established evaluation tool called the British Isles Lupus Assessment Group based Composite Lupus Assessment (BICLA). To meet the primary endpoint defined as a statistically significant and meaningful reduction in disease activity, BICLA requires improvement in organs affected by lupus with no new flares.

*“The Lupus Research Alliance has made significant investments in research focused on the role of type I interferons in lupus, and I am personally very excited given my own research in this area,”* said Dr. Mary Crow, Co-chair of the Lupus Research Alliance Scientific Advisory Board.

## Lupus News Corner



20th Annual Jets Kickoff Luncheon

### New York Jets Score Big

The New York Jets hosted their 20th Annual Kickoff Luncheon at Cipriani Wall Street August 26th—helping to raise more than \$750,000 to benefit both the New York Jets Foundation and the Lupus Research Alliance.

*"This is the 20th year we've done this, so this is a milestone," said **Christopher Johnson**, CEO and chair of the New York Jets. "It's our chance to get our entire football team together, the coaches, our fans and supporters. It's our team but it's also a community. It's so important that we do well, but part of that is being a great part of this community and giving back."*

### Power Walker or Stroller ... Take Steps to Cure Lupus

New Yorkers from all walks of life are planning to participate in the **Walk with Us to Cure Lupus** event in NYC on Saturday, October 12, 2019. The meeting place is the Intrepid Sea, Air & Space Museum at West 46th Street and 12th Avenue. Registration opens at 8:00 AM.

New Yorkers know how to do it! Last year they came together through this event and raised more than \$1 million to help help advance innovative research programs funded by the LRA.



### Save the Date: Lupus Gala

**Date:** Monday November 25, 2019  
**Place:** Ziegfeld Ballroom—141 West 54th Street, New York City  
**Honoring:** Alfred F. Kelly, Jr., Chairman and CEO, Visa Inc.  
Molly McCabe, Co-Founder, The Former Molly's Fund Fighting Lupus Community Leader  
**Entertainment:** Laura Benanti

For more information, please call 212.888.7003

Visit [lupusresearch.org](http://lupusresearch.org) to make a donation, learn more about lupus and our funded lupus research, or find out about our *Walk with Us to Cure Lupus* program.



100% of all donations goes to support lupus research programs because the Lupus Research Alliance Board of Directors funds all administrative and fundraising costs.

For the latest, up-to-date information about lupus you can join our online community on:



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