

Autoimmune diseases - Systemic Lupus Erythematosus

MEDSENIC announces the publication of its positive results for its phase IIa study (Lupsenic) in Arthritis Research and Therapy

<https://arthritis-research.biomedcentral.com/articles/10.1186/s13075-021-02454-6>

- *With cardiac and hepatic safety.*
- *Rapid return to normal of the dysfunctional immune system.*
- *Favorable safety profile of the arsenic trioxide (ATO) treatment.*
- *Important reduction of corticosteroids.*

New tandem pre-clinical data on the mechanism of action and efficacy of Arscimed

- *Decreased proteinuria and glomerulonephritis, rapid return to normal of dysfunctional immune system and improved survival in spontaneous autoimmune mouse model (NZ/BW mice)*
- *Corrected autoimmune symptoms in diseased mice and new insights into the mechanism of action (sle1,2,3 triple transgenic mice)*

These robust safety and efficacy data pave the way for launching of a phase IIb/III trial to be conducted by Medsenic, in a partnership framework

Strasbourg, France, May 17, 2021 - Medsenic, a clinical-stage biopharmaceutical company specializing in the discovery and development of new indications and formulations of arsenic salts for the treatment of severe autoimmune diseases, announces today concordant positive results in two pre-clinical studies, with Arscimed®, an IV formulation of arsenic trioxide, in in vivo models of Systemic Lupus Erythematosus (SLE).

These in vivo results reinforce the proof of the drug concept success obtained in the LUPSENIC phase IIa clinical trial conducted by the Nantes University Hospital in 7 clinical centers in France. The primary endpoint of the controlled, open-label, dose-escalation study was to demonstrate cardiac and hepatic safety in patients, and the secondary endpoint sought initial clinical efficacy. Both criteria were met, in particular clinical efficacy according to the SLEDAI clinical scoring system with a significant decrease in corticosteroids used as standard therapy.

"We are very pleased with the convergence of our preclinical and clinical results. They reinforce our determination to enter into a type II/III clinical phase, within the framework of a partnership to be concluded, in accordance with our objectives" declares Prof. François Rieger, President and co-founder of Medsenic, adding "we have already achieved several major objectives in this complex autoimmune disease. These results confirm the relevance of our innovative approach and reinforce the legitimacy of the therapeutic development of our product Arscimed® and any new formulations for the treatment of Systemic Lupus Erythematosus.

The two studies, in established animal models of lupus, were conducted by Medsenic to reach a clear understanding of the mechanism of action of Arscimed and to highlight the biological parameters related to the observed correction of severe autoimmune symptoms.

In a first study, conducted in the spontaneous autoimmune NZ/BW mouse model, Medsenic observed that mice in the group treated with Arscimed® intraperitoneal or intravenous injections did not lose weight, had reduced proteinuria and glomerulonephritis, and had a better survival rate. With a short administration of the drug, Arscimed provides a rapid return to normal for the dysfunctional immune system. These results confirm previous observations in pre-clinical MRL/lpr models, which have a near-normal lifespan after a few week treatment.

The second study, conducted by Medsenic in collaboration with the Catholic University of Leuven, using the triple transgenic *sle1,2,3* mouse model, provides new insights into the correction of autoimmune symptoms in diseased mice and unravls further the mode of action of Arscimed®.

These new results on the mechanism of action of Arscimed® confirm its potential interest in the treatment of the complex pathogenic processes leading to Systemic Lupus Erythematosus, and the possibility of extending its indication to very severe forms of lupus nephritis

About Arscimed®

The active pharmaceutical ingredient (API) of Arscimed® is arsenic trioxide. Medsenic has harnessed its expertise to develop and manufacture its own formulation of arsenic trioxide, for IV injections. Arsenic trioxide belongs to a new class of drugs able to radically modify the autoimmune cascade and normalise the immune system without causing widespread non specific immunosuppression.

A basic action of arsenic trioxide is the activation of a strong oxidative stress-induced pathway in activated immune cells, leading to the elimination of certain subtypes of pathogenic immune cells responsible for the autoimmune symptoms. It also suppresses abnormal biological processes associated with immune disorders, such as the excessive production of proinflammatory cytokines and specifically Interferon alpha.

About Systemic Lupus Erythematosus

Lupus is an autoimmune disease that affects between 20,000 and 40,000 people in France, and nearly 4 million worldwide, all forms of lupus combined, mostly women of childbearing age. There are at least two types of lupus: purely cutaneous lupus and systemic lupus erythematosus, a chronic autoimmune disease that can potentially affect any organ or tissue. Poorly known to the general public, this disease is very disabling and threatens the life of patients in 5 to 10% of cases. Systemic Lupus Erythematosus results from profound abnormalities in the functioning of the immune system. Its causes are still poorly understood, ranging from complex genetic factors to the probable role of the environment, in particular certain bacterial or viral infections.

To date, there is no cure for any form of Lupus.

About Medsenic

Medsenic is innovating and exploiting the new possibilities offered by the therapeutic use of arsenic trioxide in several autoimmune diseases and is currently in the process of clinical studies in Europe. The company was created in 2010 by Prof. François Rieger, former Research Director CNRS, author of more than 170 international scientific publications, and Véronique Pomi-Schneiter, former founder and manager of a consulting company in human resources, communication and development strategies. Under the aegis of a high-level scientific council, chaired by the 2011 Nobel Prize for Medicine Jules Hoffmann, a specialist in Innate Immunology, and supported by a solid core of private investors, Medsenic accelerated its development in 2016 with the financial support of institutional investors, Cap Innov Est, Fa Dièse and CNRS Innovation SA.

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