



MEDSENIC announces the completion of patient enrollment in its Phase II clinical trial in the Chronic Graft Versus Host Reaction, and clarifies the development of its drug Arscimed® (arsenic trioxide)

- *The study GMED16-001, on the treatment of chronic GvHD with Arscimed®, is currently being completed, with the inclusion of the last patient in June 2019.*
- *The objective of clinical trial is to obtain evidence of an optimal benefit/risk ratio for intravenous (IV) treatment with a positive partial and/or complete response rate at 6 months (Primary Endpoint) after diagnosis of cGvHD (Chronic Disease of the Graft Host).*
- *Clinical prospects are confirmed with the preparation of a Phase III clinical study with a comparator arm with the reference treatment (corticosteroids alone)*

Strasbourg, France, November 20, 2019 - MEDSENIC, a French biopharmaceutical start-up, announces that it has completed the recruitment of all patients planned for its multicenter Phase 2 first-line clinical trial, in addition to prednisolone, with the secondary (and important) goal of gradually eliminating it.

Current observations confirm development plan a Phase III trial which, if successful, would allow the product to be registered in Europe and the United States.

Preliminary data for the Phase II study is expected in the summer of 2020.

The completion of the clinical and commercial development of Arscimed® in cGVhD (Access to Market) has been discussed with the European (Scientific Advice of the EMA) and American authorities (preIND (Investigational New Drug) meeting at the FDA (Food and Drug Administration)) in recent months.

According to **Prof. François Rieger, President of MEDSENIC**, *"the clinical and regulatory advances now achieved are very significant regarding bringing to market an effective treatment for this often fatal disease, currently without curative treatment. We can now anticipate the development of a successful treatment for chronic GvHD, by performing a Phase 3 clinical trial confirmatory of all our recent observations. The protection and specific status offered by the orphan designations, previously granted by the American and European authorities, now allow us to confidently consider the completion of clinical development and market access for a new version of this innovative treatment using arsenic trioxide."*

About Arscimed®:

Arscimed is a drug whose pharmacologically active ingredient is arsenic trioxide. The expertise and manufacturing for IV injection are mastered by Medsenic. This drug belongs to a new class of molecules able to radically modify the autoimmune cascade and modulate the functioning of the immune system, bringing it back to normal, with no features of non specific immunosuppression. Arsenic trioxide mainly activates a strong oxidative stress pathway in activated immune cells, and allows the elimination of certain subtypes of pathogenic cells from the immune system. It further

corrects abnormalities in some of the biological parameters that characterize abnormal immune function, such as an excess of proinflammatory cytokines.

About cGvHD

cGvHD - Chronic Graft versus Host Disease - is a complex autoimmune reaction that develops following bone marrow transplants or, more precisely, allogeneic hematopoietic stem cells, with a frequency of 30-60 % of the treated patients. It affects each year approximately 16,000 people in the European Union and 20,000 in the United States and Canada, which places it under the classification of Orphan Disease.

After grafting, the donor immunocompetent cells often trigger an immune response against the recipient - called the "Host". They will recognize the recipient's own antigens as foreign and will seek to destroy them. The donor's T cells thus attack the host's tissues and organs. This phenomenon can even be observed between donor and host who are very close immunologically. This disease remains a major obstacle to therapeutic transplants in hemato-oncology...

A so-called acute GvHD occurs in the weeks following transplantation. After a certain period of time, the reaction changes in nature and displays autoimmune disease characteristics. It becomes chronic, with a continuous aggravation, often uncontrolled by conventional immunosuppressive treatments, and has a poor prognosis, making cGvHD potentially fatal. This is why there is an urgent need for new therapeutic approaches.

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 professional investors, Cap Innov'Est, Fa Dièse and CNRS Innovation SA.

www.medsenic.com

Press Contact:

MEDSENIC

Véronique Pomi-Schneiter,
Executive Director

00336 35 46 32 66 - veronique.pomi@medsenic.com