Medsenic publishes an article in *Transplantation and Cellular Therapy,* unveiling

High response rate and corticosteroid sparing with arsenic trioxide-based first-line therapy in cGvHD after allo-HSCT

- *First-line combination of arsenic trioxide and prednisone in cGvHD showed an Overall Response Rate (ORR) at 6 months of 75%, allowing rapid corticosteroid tapering.*

- *Skin and eating disorders significantly improved whereas other dimensions of quality of life did not change.*

- *In murine models of cGvHD, arsenic trioxide (ATO) increases oxidative stress and regulates T and B cell populations and macrophage polarization.*

Strasbourg, France, July 18th 2022 – Medsenic, a clinical stage biopharmaceutical company focusing on the discovery and development of new indications and formulations of arsenic salts for the treatment of severe autoimmune diseases, announced today a new publication in *Transplantation and Cellular Therapy*, - the official Journal of ASTCT (American Society for Transplantation and Cellular Therapy)- that provides insights from its drug Arscimed®, a GMP intravenous formulation of arsenic trioxide, in patients with Chronic Graft Versus Host Disease (cGvHD).

High response rate and corticosteroid sparing with arsenic trioxide-based first-line therapy in cGvHD after allo-HSCT - Transplantation and Cellular Therapy, Official Publication of the American Society for Transplantation and Cellular Therapy (astctjournal.org)

« *This Phase II study shows a growing body of data demonstrating the robust response generated by the first-line combination of our arsenic product Arscimed and corticosteroids and how it is associated with a high clinical response rate and rapid CS sparing in cGvHD after previous allo-HSCT. These excellent results are a promising step forward to the management of patients with cGvHD, a rare, complex and extremely debilitating autoimmune disease affecting over 40,000 people worldwide and for which there is no satisfactory treatment. We look forward to confirming its efficacy in a Phase III study as well as its significant impact on improving the quality of life of cGvHD patients"* said **Prof. François Rieger, President and co-founder of Medsenic**.

The primary endpoint of this prospective Phase II multicentre, non-randomised study was the improvement of treatment response, i.e., **complete or partial disease remission 6 months after cGvHD diagnosis**, with the active ingredient ATO in combination with prednisone, with or without cyclosporine.

Back in May 2022, Medsenic received positive pre-IND response from FDA to initiate a Phase III Clinical Study in cGvHD, with an oral formulation of ATO (OATO, chosen commercial name: ArsciCor).

About OATO/ArsciCor

Medsenic GMP-qualified arsenic trioxide, obtained by new *de novo* synthesis from the chemical elements As and O, has been formulated for oral administration (capsules). This novel formulation is protected by international patents, and Medsenic holds an exclusive license and extensive marketing rights, particularly for the chronic graft versus host disease indication, which is its lead disease target. The OATO formulation (ARSCICOR for autoimmune applications) offers major advantages for clinicians and patients. It is associated with rapid gastrointestinal solubilization, optimal bioavailability comparable to the intravenous formulation (ARSCIMED in the Phase II study), less adverse effects and recently demonstrated bioequivalence in the very rare condition, acute promyelocytic leukemia.

About cGvHD

cGvHD - Chronic Graft versus Host Disease - is a complex autoimmune reaction that develops following bone marrow allogeneic hematopoietic stem cell transplants, with a frequency of 30-60%. It affects about 16,000 people in the European Union and 20,000 in the United States and Canada, which places it under the designation of Orphan Disease.

After transplantation, the immunocompetent cells contained in the graft often trigger an immune reaction against the recipient - the so-called "host". They consider the recipient's own antigens as foreign and seek to destroy them : the donor's T-cells attack the recipient's tissues and organs. This phenomenon is observed even between donors and recipients who are immunologically very close and remains a major obstacle to therapeutic transplants in hemato-oncology.

Often acute cGvHD occurs in the weeks following transplantation. After a certain period of time, the reaction changes in nature and presents characteristics of an autoimmune disease. It becomes chronic, with a worsening that is generally uncontrolled by conventional immunosuppressive treatments, with a poor prognosis, making cGvHD potentially fatal. Hence the 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 clinical trials in Europe. The company was founded in 2010 by François Rieger, former Director of Research at the CNRS (French National Center for Scientific Research), author of more than 170 international scientific publications, and Véronique Pomi-Schneiter, former founder and manager of a consulting firm specializing in human resources, communication and development strategy. Under the aegis of a high-level scientific board, chaired by the 2011 Nobel Prize in Medicine

Jules Hoffmann, specialist in innate immunology, and supported by numerous private investors, Medsenic is rapidly expanding and in2021 welcomed the Australian company PHEBRA Pty as a minority shareholder.

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