# Medsenic partners with Phebra for the clinical development of the oral form of Arscimed® for the treatment of autoimmune diseases.

- Exclusive licensing agreement for the development of a patented formulation of oral arsenic trioxide in the treatment of autoimmune diseases
- Initially the oral formulation of arsenic trioxide (Arscimed) will target the treatment of ambulatory patients with chronic graft-versus-host disease (cGvHD)
- The bioavailability of the oral form is equivalent to that of the intravenous formulation as validated in a clinical study in a cohort of cancer patients
- A major step that will facilitate the launch of a Phase 3 clinical trial for ambulatory patients with cGvHD
- Other autoimmune diseases will be entered into the Medsenic clinical development program on the back of an additional fundraising

**Strasbourg, France, June XX, 2021** - Medsenic, a clinical-stage biopharmaceutical company focused on the discovery and development of novel indications and formulations of arsenic salts for the treatment of severe autoimmune diseases, announced today that it has entered into an exclusive licensing agreement with Australian company Phebra for the development of their patented OATO formulation (Oral Arsenic Trioxide) in the treatment of autoimmune diseases.

This agreement is a major step in paving the way for the marketing of a second generation of Medsenic's drug candidates, until now dispensed as an intravenous solution (Arscimed®). Phebra's expertise in drug development, together with Medsenic's clinically validated scientific discoveries, will confirm further the efficacy of arsenic trioxide observed in a phase 2 study, by switching to the novel and patient administered oral form (OATO).

"*We are delighted with this partnership with Phebra, a global reference player renowned for its unique expertise in the development and formulation of critical care medicines and a specific expertise in arsenic-based drugs. This exclusive agreement reflects Medsenic's commitment to pursue the development of its pipeline of drug candidates targeting*

*autoimmune diseases ; it will allow us to initiate our Phase 3 clinical trial for the treatment of cGvHD and to develop our products in new indications such as systemic sclerosis*", said **Prof. François Rieger, President and co-founder of Medsenic**, who added: "*The robust formulation of Arscimed® is a real paradigm shift in that it will bring expected comfort to patients with chronic graft-versus-host disease*."

"*We are impressed by the clinical results obtained by Medsenic with its product Arscimed in the treatment of cGvHD as an intravenous solution. We are confident that the properties of arsenic trioxide observed in various clinical studies have the potential to revolutionize the therapeutic management of autoimmune diseases where there remains a huge unmet medical need. With our novel patented oral formulation, we will contribute to a significant improvement in patient care, avoiding frequent hospital stays, painful injections and potentially less adverse side effects*," said Dr **Mal Eutick, President of Phebra**.

**About the ATO :**

Arsenic trioxide has the dual property of increasing cellular oxidative stress, to the point where it induces the programmed death of activated cells (enhanced apoptosis) and of modulating their production of proinflammatory cytokines. It thus has a specific long-term immunomodulatory effect on activated cells of the innate immune system, without affecting its normal components, as demonstrated in animal models without autoimmune pathology, and with perfectly controlled side effects. It probably acts at an upstream coordination level of the immune cascade, since a correction of all parameters signaling the autoimmune cascade is observed in various animal models of autoimmunity.

Research programs are being developed to understand the positive effects of arsenic trioxide in human clinical trials. MEDSENIC has provided initial proof of concept in a Phase 2a clinical trial for the treatment of severe systemic lupus erythematosus, followed by positive results in the treatment of cGvHD in Phase 2 (75% success rate in the full analysed population). Medsenic has demonstrated that its arsenic trioxide-based treatment has minimal toxicity and proven efficacy, leading to its wider application in other autoimmune diseases.

**About Medsenic -** www.medsenic.com

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.

**About Phebra:**

Phebra is an Australian based specialty pharmaceutical group which develops, manufactures and markets critical medicines in Australia and across the world. At Phebra, we create critical medicines that save and improve lives.

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