Medsenic Receives Positive Pre-IND Response from FDA to Initiate a Phase III Clinical Study in cGvHD

Strasbourg, France – June 20th, 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 the positive conclusions of the pre-IND (Investigational New Drug) meeting with the US Food and Drug Administration (FDA).

Medsenic's proposed protocol with OATO (oral arsenic trioxide) was received favorably by the FDA. Following the implementation of a few improvements suggested by the agency, the protocol can be submitted as an IND application for our Phase III clinical study in chronic graft versus host disease (cGvHD).

This feedback from the FDA is based on the positive results of the Phase II clinical study GMED16-001 with Arscimed® IV. The primary endpoint of this prospective, multicenter, non-randomized study was the improvement of treatment response with Arscimed® in combination with prednisone, with or without cyclosporine. **Complete or partial disease remission was obtained 6 months after GvHD diagnosis and maintained at 12 months.**

Medsenic is focusing its clinical activities on the development of OATO (oral arsenic trioxide) for the treatment of selected autoimmune diseases.

Consequently, preparations for the Phase III study are progressing as planned, with a launch expected early 2023. This randomized, double-blind, placebo-controlled Phase III study will assess the efficacy and safety of oral arsenic trioxide (OATO) as first-line treatment for cGvHD.

Prof. François Rieger, President and co-founder of Medsenic, said: "*We are pleased with the promising pre-IND response from the FDA. This is a very important step towards a clinical application of our OATO drug candidate for the treatment of cGvHD. An interim analysis is planned halfway through our Phase III study, and if positive, these first results will help us plan for an accelerated approval for the oral drug*."

The convenient administration and increased safety of this oral formulation constitute a major advance in the treatment of autoimmune diseases with so far unmet medical needs.

About OATO

Our GMP-qualified arsenic trioxide, obtained by *de novo* synthesis from the chemical elements As and O, has been formulated for oral administration. This novel formulation is protected by international patents, and Medsenic holds an exclusive license and extensive marketing rights for the chronic graft versus host disease indication, which is its primary 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), and recently demonstrated bioequivalence in the very rare condition of acute promyelocytic leukemia.

About cGvHD

cGvHD - Chronic Graft versus Host Disease - is a complex autoimmune reaction that develops following bone marrow or more precisely 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 thus 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.

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 often 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 Hoffman, specialist in innate immunology, and supported by numerous private investors, Medsenic is rapidly expanding and in 2021 welcomed the Australian company PHEBRA Pty. as a minority shareholder.

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