Medsenic, a subsidiary of BioSenic, has received a key European patent approval from the EPO for the use of ATO (arsenic trioxide) in treating multiple sclerosis.

Mont-Saint-Guibert, Belgium, November 27, 2024, 6:00 PM CEST – BIOSENIC (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in severe autoimmune and inflammatory diseases, announces that its subsidiary Medsenic has secured a new patent (B180218EP), which will be published on December 25, 2024, on the European Patent Office (EPO) website. The European patent application No. 18722530.5, filed on May 4, 2018, pertains to a "Method for treating multiple sclerosis using arsenic."

Multiple sclerosis (MS) is a neurodegenerative autoimmune disease that affects the brain, spinal cord, and optic nerves. It leads to the degradation of the protective sheath surrounding and nourishing neurons, which are essential for transmitting information between the brain and the rest of the body. In France, over 130,000 individuals are affected by MS, with 1 million cases in Europe and 2.8 million worldwide. To date, there is no cure for multiple sclerosis.

This key patent, specific to MS, granted by the EPO, aligns with BioSenic's intellectual property strategy, which includes additional patent applications in other regions. These patents will support BioSenic's implementation of international clinical trials for autoimmune diseases with significant unmet medical needs. These trials aim to generate clinical data that will further enable market access approvals.

François Rieger, PhD, CEO of Medsenic, states:
"The new patent granted to Medsenic, with its validation by the EPO officially scheduled for 25/12/2024, has been issued for the 38 contracting states of the European Patent Convention. It opens a new pathway for testing a promising treatment for the relapsing form of Multiple Sclerosis, the most commonly diagnosed type in developed countries, with a marked North-South gradient, as Northern countries are the most affected. While this disease is currently treated with numerous therapies that often slow or mitigate its severity, no long-term cure exists. We believe we have a valuable treatment capable of inducing long-term immune tolerance, with manageable known side effects, unlike, for example, corticosteroids."

The anticipated production of an oral formulation of arsenic trioxide positions Medsenic uniquely to capitalize on its previously successful clinical trials in treating lupus and graft-versus-host disease (GVHD). Multiple Sclerosis (MS), a disease currently without a definitive cure, could be the focus of a Phase 2 clinical trial using this oral formulation.

Additionally, with a newly patented formulation in 2023 (B190079), protected across Europe, Japan, China, Australia, Canada, Russia, and the USA, Medsenic is poised to advance clinical development with an oral formulation containing lower arsenic content. This innovative formulation significantly reduces side effects, further enhancing its potential therapeutic value.

About BioSenic

BioSenic is a leading biotech company specializing in the development of clinical assets issued from its Medsenic's arsenic trioxide (ATO) platform. Key target indications for the autoimmune platform include graft-versus-host-disease (GvHD), systemic lupus erythematosus (SLE), and now systemic sclerosis (SSc).

Following the merger in October 2022, BioSenic combined the strategic positionings and strengths of Medsenic and Bone Therapeutics. The merger specifically enables Medsenic/Biosenic to develop an entirely new arsenal of various anti-inflammatory and anti-autoimmune formulations using the immunomodulatory properties of ATO/oral ATO (OATO).

BioSenic is based in the Louvain-la-Neuve Science Park in Mont-Saint-Guibert, Belgium. Further information is available at http://www.biosenic.com.

About the main Medsenic/BioSenic technology platform

*The **ATO platform** provides derived active products with immunomodulatory properties and fundamental effects on the activated cells of the immune system. One direct application is its use in onco-immunology to treat GvHD (Graft-versus-Host Disease) in its chronic, established stage. cGvHD is one of the most common and clinically significant complications affecting long-term survival of allogeneic hematopoietic stem cell transplantation (allo-HSCT).*

*Medsenic has been successful in a phase 2 trial with its intravenous formulation, **Arscimed®**, which has orphan drug designation status by FDA and EMA. The company is heading towards an international phase 3 confirmatory study, with its new, IP-protected, OATO formulation. Another selected target is moderate-to-severe forms of systemic lupus erythematosus (SLE), using the same oral formulation. ATO has shown good safety and significant clinical efficacy on several affected organs (skin, mucosae, and the gastrointestinal tract). Systemic sclerosis is now full part of the clinical pipeline of Medsenic/BioSenic. This serious chronic disease badly affects skin, lungs, or vascularization, and has no current effective treatment. Preclinical studies on pertinent animal models are positive, giving good grounds to launch a phase 2 clinical protocol, using new immunomodulatory formulations of APIs recognized to be active on the immune system.*

The company is currently focusing its present R&D and clinical activities on a selective, accelerated development of its autoimmune platform.

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