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Medsenic receives the intention to grant a key European patent from EPO, valuable for the therapeutic development of arsenic trioxide in relapsing-remitting multiple sclerosis

Medsenic's experimental drug, arsenic trioxide, can now be investigated for the treatment of multiple sclerosis through repeated cycles of administration by multiple routes, including intravenous, oral and other innovating routes of administration.

Mont-Saint-Guibert, Belgium, August 14, 2024, 7.00am CET – BioSenic (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases, today announces that the European Patent Office (EPO) has granted an important new EU patent to its subsidiary Medsenic entitled: METHOD FOR TREATING RELAPSING-REMITTING MULTIPLE SCLEROSIS USING ARSENIC TRIOXIDE (EP18722530, priority date May 4, 2018).

Medsenic had earlier sponsored a preclinical study showing that a well-known and accepted mouse model of multiple sclerosis, which exhibits inflammatory and degenerative features reminiscent of human RRMS, could delay the onset of the disease or treat it. This preclinical model (Experimental Allergic Encephalomyelitis: EAE) is induced by MOG35-55/CFA immunization and pertussis toxin injection in C57BL/6 mice and allows to study the effects of ATO on the inflammatory processes active in early MS development (RRMS), thus focusing on the early manifestations of RRMS. These data had previously supported the granting of a USPTO patent (US10716807), protecting the same application in the US. The present extension will facilitate projects to license and develop phase 2-3 clinical trials for the most prevalent form of Multiple Sclerosis, RRMS.

BioSenic has also recently published data on the mechanism of action of arsenic trioxide (ATO), which gives further grounds to understand its immunomodulatory effects on inflammation. These data, published in peer-reviewed international journals in 2022 and 2023, now allow Medsenic to develop the use of various formulations of Arsenic trioxide, including new innovating combinations with excipients or APIs, opening a wider field of applications, particularly in the fields of autoimmunity, infectious diseases and cancer.

The expected EU patent allows the specific application of Medsenic's arsenic platform to the key human health indication, Multiple Sclerosis. This patent is part of Medsenic/BioSenic's extensive efforts to conduct international clinical trials in pathologies with clear unmet medical needs, using all the potential of ATO based treatments.

François Rieger, PhD, Chairman and CEO, BioSenic said: *"BioSenic's new EPO patent, which will be granted for the 27 European countries, opens new perspectives in the attempt to control the pathological effects of a terrible disease, multiple sclerosis. This new potential use of our drug is part of our efforts to provide a unified treatment for a number of diseases that fall within the realm of innate, adaptive and acquired immunity. These diseases affect a significant percentage of the world's population. Autoimmune diseases lead to chronic illnesses with all too often poor prognosis and lack of medical support. Diseases of interest to Medsenic/BioSenic include chronic graft versus host disease, systemic lupus erythematosus (SLE) and systemic sclerosis. The anticipated availability of an oral formulation combining arsenic with potentially other active ingredients puts Medsenic/BioSenic in a unique position to build on its recent clinical successes in SLE and Graft versus Host Disease therapy in other indications, such as Multiple Sclerosis."*

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.

Note: The allogeneic cell therapy platform-originating from the previous listed company Bone Therapeutics company, may be of renewed interest by using isolated and purified differentiated bone marrow Mesenchymal Stromal Cells (MSCs) as a starting material for further isolation of passive or active biological subcellular elements. Indeed, these cells may provide new subcellular vesicles potentially able to deliver a unique and proprietary approach to organ repair. BioSenic is involved in determining new patentable approaches in this complex area of cell therapy.

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