

## Medsenic, subsidiary of BioSenic SA, extends key patent to the United States

- **The developed Medsenic's composition-of-matter patent family does cover the therapeutic use of arsenic salts and metal ions through various routes of administration.**
- **Medsenic's enriched IP portfolio is aimed at protecting medications involving the combination of arsenic trioxide (ATO) and copper ions, which have demonstrated increased therapeutic potential for indications ranging from immune to cancer and to infectious diseases.**

**Mont-Saint-Guibert, Belgium, July 5, 2024, 7.00am CET – BioSenic (Euronext Brussels and Paris: BIOS)**, the clinical-stage company specializing in serious autoimmune and inflammatory diseases and cell repair therapy, today announces the filing of the continuation patent application US 18/763,376 with the United States Patent & Trademark Office (USPTO) to provide protection for the use of arsenic trioxide (ATO) for the prevention and treatment of sepsis syndrome. The patent application seeks to cover the use of Medsenic's ATO platform, to prevent or alleviate the cytokine storm associated with systemic infections of various origins but sharing a common set of key symptoms (such as persistent hypotension, hyperthermia or hypothermia, leukocytosis or leukopenia, and thrombocytopenia) with dramatic short-term health consequences. Similar protection may lead to the filing of further specific divisional applications, in particular at the European Patent Office (EPO).

Medsenic SAS, subsidiary of BioSenic SA, is exploring the therapeutic use of ATO in several indications with clinical success. The company is also making significant progress in elucidating the mechanisms by which ATO modulates immune responses and the ability of certain metal ions to enhance this therapeutic potential. The ever-growing intellectual property portfolio is part of a strategy to build strong and meaningful protection around its lead product, ATO, paving the way for clinical and commercial development by the company and its partners, particularly in the field of autoimmunity.

The new patent, now being extended by Medsenic in the USA, covers two main areas of immediate application. The first is in immune- and autoimmune-related diseases - specifically BioSenic's current lead project, chronic GvHD, and later systemic sclerosis and systemic lupus erythematosus. The second is oncology, where ATO has already demonstrated exceptional results in patients, including complete remissions in acute promyelocytic leukaemia. The growing patent family will support Medsenic/BioSenic's plans for international clinical trials in pathologies with unmet medical needs. The company's long-term goal is to seek market access approvals for its various formulations, optimizing the original properties of arsenic salts, alone or in combination.

**François Rieger, PhD, Chairman and CEO of BioSenic said:** *"The current effort to improve the field of indications and a broader intellectual property for the use of original formulations and composition of matter related to the extraordinary properties of arsenic salts should give a dramatic impetus to the clinical and commercial development of the company. Arsenic salts are now found to exhibit critical and very original biological properties that should help provide new ways to treat diseases of the immune system and, further, cancer conditions with no effective medical treatment. It is of great interest that pharmacological formulations containing arsenic salts are often found to redirect organisms towards normal functioning of various cells and organs and restore homeostasis. We are delighted to be opening new chapters in the continuing global effort to control chronic or fatal diseases for which there is no real cure."*

The expected availability of both an intravenous and an oral formulation combining arsenic and copper puts BioSenic in a unique position to build on preclinical successes in chosen areas of applications. Medsenic/BioSenic should be able to continue a successful clinical development involving proprietary original formulations with arsenic and new active ingredients such as metal ions- increasing the efficacy of its products and minimizing side effects.

Medsenic's worldwide patent family already includes a patent granted by the European Union Intellectual Property Office (EP3972613) in April 2023, and others by the China National Intellectual Property Administration in August 2023, by the Australian Patent Office in December 2023 and by Canada in January 2024 (3,138,472).

### 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, **Arcsimed®**, 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 now involved in determining new patentable approaches in this complex area of cell therapy.

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