Medsenic/BioSenic patent granted in Japan for more protection of its therapeutic platform

- **Composition-of-matter patent covers the therapeutic use of arsenic salts and metal ions through various routes of administration.**
- **Enriched IP portfolio protects arsenic trioxide (ATO) use combined with copper ions delivery, which has demonstrated increased therapeutic potential for indications ranging from immune to cancer and infectious diseases.**

Mont-Saint-Guibert, Belgium, August 13, 2024, 6.00pm CET – BioSenic (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases, today announces the granting of a key patent by the Japan Patent Office to expand protection of the arsenic trioxide (ATO) platform. The patent, titled "Use of metal ions to potentiate the therapeutic effects of arsenic," covers the use of ATO platform in combination with metal ions such as copper. This combination has shown the ability to significantly improve the treatment of autoimmune diseases and could be applied to the treatment of various forms of cancer conditions and infectious pathologies related to cytokine storms. Similar protection had been granted in Europe and Australia last year, together with a first patent acceptance in China, which opened the doors for further divisional applications in addition to the primary decision limited to graft-versus-host disease (GvHD).

BioSenic is exploring the therapeutic use of ATO for several indications. The company has recently published peer-reviewed data from several preclinical studies elucidating ATO's mechanisms for modulating immune responses, and the ability of certain metal ions to enhance this therapeutic potential. The actual growing portfolio of intellectual property rights is part of a strategy to build dense and meaningful protection for its lead product, paving the way for clinical and commercial developments by BioSenic and interested partners, particularly in the field of autoimmunity.

The new patent, granted to BioSenic's subsidiary company Medsenic, involves two main immediate areas of application. The first one is in immune- and autoimmune-related diseases – specifically, the BioSenic's lead project in 2024, chronic GvHD and, later, systemic sclerosis and systemic lupus erythematosus. The second is in oncology, where ATO has already demonstrated exceptional results for patients, including complete remission in acute promyelocytic leukaemia. These patents will support BioSenic's plans for international clinical trials in pathologies with unmet medical needs, toward the company's long-term goal of seeking 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: *"This newly granted regional patent for Japan further consolidates our intellectual property rights on the formulations and compositions of matter related to the first-in-class properties of arsenic salts, which we find to generally reorient organisms toward normal function and homeostasis in various cells and organs. We are happy to open new chapters in the continuous, worldwide effort in trying to control chronic or lethal diseases with no real cure."*

The expected availability of an oral formulation that combines arsenic and copper puts BioSenic in a unique position to build on clinical successes in its fields of applications. As a result, BioSenic will be able to continue clinical development with proprietary original formulations containing arsenic and new active ingredients such as metal ions, increasing the potency of its products, and minimizing secondary side effects.

The Japanese patent, corresponding to Application 2021-569115 filed on May 20, 2020, is now granted to Medsenic, a subsidiary of BioSenic. Similar regional patents on the same subject were granted by European Union Intellectual Property Office (EP3972613) in April 2023, by China National Intellectual Property Administration in August 2023, and by the Australian and Canadian Patent Offices in December 2023.

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 now involved in determining new patentable approaches in this complex area of cell therapy.

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