

BioSenic patent granted in Canada for broader protection of ATO 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, 30 January 2024 – BioSenic (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases and cell repair therapy, today announces the granting of a key patent by the Canadian Intellectual Property 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 a number of 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 on, 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 patent in Canada further structures our intellectual property rights on the formulations and compositions of matter related to the extraordinary 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 Canadian patent, corresponding to Application 3,138,472, was granted to Medsenic, a subsidiary of BioSenic. The similar patents were granted by European Union Intellectual Property Office (EP3972613) in April 2023, by China National Intellectual Property Administration in August 2023, and by Australia Patent Office in December 2023, respectively.

About BioSenic

BioSenic is a biotech company specializing in the clinical development of autoimmune disease therapies. Following a reverse merger in October 2022, BioSenic combined its strategic positioning, key strengths and strong IP to develop products along two tracks, separately and in combination. The first platform leverages immunomodulatory properties of arsenic trioxide (ATO) for an entirely new arsenal of

formulations, including oral delivery (OATO), for anti-inflammatory and anti-autoimmune indications such as chronic graft-versus-host disease (cGvHD), systemic lupus erythematosus (SLE) and systemic sclerosis (SSc). In parallel, BioSenic develops innovative products through a second platform that includes cell therapies and strong IP protection for tissue repair technologies. 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 BioSenic's technology platforms

The ATO platform has immunomodulatory properties with fundamental effects on the activated cells of the immune system. One direct application is its use in autoimmunity to treat in its chronic, established stage. Chronic GvHD is one of the most common and clinically significant complications affecting long-term survival of allogeneic hematopoietic stem cell transplantation (allo-HSCT), a curative treatment for patients with serious blood diseases, including cancers.

BioSenic's intravenous ATO formulation, Arscimed(R), has orphan drug designation status by FDA and EMA, and it has shown good safety and significant clinical efficacy for skin, mucosae, and the gastrointestinal tract in an early Phase 2a study. The company is planning a confirmatory international Phase 3 study with its oral ATO (OATO) formulation. OATO will also target moderate-to-severe forms of SLE. BioSenic is also developing a new IP-protected OATO formulation for the treatment of SSc, a serious chronic disease that affects skin, lungs or vascularization, and has no current effective treatment. Preclinical studies on pertinent animal models support the launch of a Phase 2 clinical trial.

ALLOB is an allogeneic cell therapy platform made of differentiated, bone marrow-sourced mesenchymal stromal cells (MSCs), which can be stored at the point-of-use in hospitals. ALLOB represents a unique and proprietary approach to organ repair, and specifically to bone regeneration, by turning undifferentiated MSCs from healthy donors into bone-forming cells at the site of injury. BioSenic is studying the results of a Phase 2 trial to optimise the efficacy of ALLOB by determining the best timing for therapeutic intervention and seeking partners to continue the development of the promising underlying therapy strategies.

The company is also exploring partnerships at all levels for its JTA-004 viscosupplement for a severe inflammatory subtype of osteoarthritis, following a positive post hoc analysis of Phase 3 data demonstrating safety and efficacy in support of this licensing.