Press Release
Media Contacts:
IB Communications
Tel +44 (0)20 89434685
biosenic@ibcomms.agency

BioSenic receives a Chinese patent with broad claims, protecting the combined use of metal ions and arsenic salts to treat a wide range of serious diseases

- **Composition-of-matter patent covers the therapeutic use of arsenic salts and metal ions through various routes of administration**
- **Enriched IP portfolio protects ATO with demonstrated therapeutic potential for indications ranging from cancer to immune or infectious diseases**

Mont-Saint-Guibert, Belgium, August 24 , 2023 – BioSenic (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases and cell therapy, today announces the issuance of a key new patent entitled 'Use of metal ions to potentiate the therapeutic effects of arsenic' to its subsidiary company Medsenic by the China National Intellectual Property Administration (CNIPA). This patent (ZL202080040613.1) covers the use of its ATO platform in combination with metal ions like copper, which has the potential to improve the treatment of autoimmune diseases. The European Patent Office (EPO) granted similar protection (EP3972613) in April 2023.

BioSenic is exploring the therapeutic use of ATO for a number of disease areas, and has recently published peer-reviewed data from several preclinical studies elucidating its mechanisms for modulating immune responses, and the ability of certain metal ions to enhance this therapeutic potential. The intellectual property rights recently secured in EU and China pave the way for clinical and commercial developments by BioSenic and interested partners, particularly in the fields of cancer and autoimmunity.

The patent involves two main immediate areas of application. The first is in immune and autoimmune related diseases such as chronic Graft-versus-Host Diseases (cGvHD), systemic sclerosis and systemic lupus erythematosus. The second is in oncology, where ATO has already demonstrated exceptional results for patients, including complete remission of acute promyelocytic leukaemia. This patent issued by CNIPA is in line with the company's general strategy of setting a dense and meaningful intellectual property portfolio. Indeed, these patents will support the BioSenic's plans for international clinical trials in pathologies with unmet medical needs, and toward the company's long-term goal of seeking market access approvals for its various formulations including the original properties of arsenic salts.

"It is remarkable that China, the home of medicinal arsenic, is validating BioSenic's discoveries and paving the way for industrial development for the treatment of diseases with clinical unmet medical needs, such as cancer, autoimmunity and infectious diseases, in Asia and elsewhere," **said François Rieger, PhD, Chairman and Chief Executive Officer of BioSenic.** "We are thrilled to open up new chapters in the continuous worldwide effort in trying to control 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 formulations containing arsenic and active new ingredients such as metal ions, minimizing secondary side effects.

About BioSenic
BioSenic is a leading biotech company specializing in the development of clinical assets issued from: (i) the arsenic trioxide (ATO) platform (with key target indications including Graft-versus-Host Disease (GvHD), systemic lupus erythematosus (SLE) and systemic sclerosis (SSc)) and (ii), the development of innovative products to meet unmet needs in orthopedics.
Following a reverse merger in October 2022, BioSenic combined a strategic positionings and strengths to use, separately and combined, an entirely new arsenal of various anti-inflammatory and anti-autoimmune formulations using the immunomodulatory properties of ATO/oral ATO (OATO) with its innovative cell therapy platform and strong IP for tissue repair protection.
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 technology platforms

BioSenic's technology is based on two main platforms:

1. The ATO platform, which has been successfully developed, has immunomodulatory properties with fundamental effects on the activated cells of the immune system. The first effect is the increase of the cell oxidative stress in activated B, T and other cells of the innate/adaptative immune system to the point they will enter a cell death program (apoptosis) and be eliminated. The second effect is potent immunomodulatory properties on several cytokines involved in inflammatory or autoimmune cell pathways, with return to homeostasis. 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). cGvHD is primarily mediated by the transplanted immune cells that can lead to severe multiorgan damage. BioSenic has been successful in a Phase II trial with its intravenous formulation, which has orphan drug designation status by FDA and EMA. The Company is heading towards an international Phase III 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) in an early Phase IIa study. Systemic sclerosis is also part of the clinical pipeline of BioSenic. This serious chronic disease badly affects skin, lungs or vascularization, and has no actual current effective treatment. Preclinical studies on pertinent animal models are positive, giving good grounds to launch a Phase II clinical protocol.
2. The allogeneic cell and gene therapy platform developed by BioSenic, with 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 stromal cells from healthy donors into bone-forming cells on the site of injury. ALLOB has recently been evaluated in a randomized, double-blind, placebo-controlled Phase IIb study in patients with high-risk tibial fractures, using its optimized production process, after a successful first safety and efficacy study (Phase 1/2a) on fractured long bones, with late-delayed union. However, in June 2023, BioSenic decided to suspend its interventional trial on fracture healing using ALLOB, following negative results obtained for the primary endpoint in this exploratory Phase IIb clinical trial, interpreted as a failure of a too early cell injection, just after fracture. BioSenic is now focusing on determining the best time to optimise the efficacy of ALLOB (choice between early or late treatment).

Note: Biosenic has reevaluated a previous important and years-long clinical development program. In March 2023, after the clinical identification of distinct OA subtypes, BioSenic delivered a new post-hoc analysis of its Phase III JTA-004 trial on knee OA, demonstrating positive action on the most severely affected patient subpopulation. This new post-hoc analysis drastically changes the therapeutic profile of the combined components and allows for better patient targeting in future clinical developments. This leads to a next-generation of JTA, off-the-shelf enhanced viscosupplement to treat knee osteoarthritis (OA), made of a unique combination of mammalian plasma proteins, derivatives of hyaluronic acid (a natural component of synovial fluid in the knee) and a third active component. JTA or some derivatives are intended to provide effective lubrication and protection to the cartilage of the arthritic joint and to alleviate osteoarthritic (OA) pain and inflammation.

The company, will nevertheless focus its present R&D and clinical activities on a selective, accelerated development of its autoimmune (ATO/OATO) platform.