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BioSenic receives key European patent from EPO, for further therapeutic development in cancer, infectious and immune diseases

Patent covers the therapeutic use of a new composite formulation of anti-inflammatory compounds with unique advantages

BioSenic's new formulation lowers the dosage of arsenic trioxide by combining it with copper salts to maintain therapeutic efficacy, with the potential of administration through multiple routes, including intravenous, oral and other novel routes of administration

Mont-Saint-Guibert, Belgium, April 18, 2023, 7.00am CET – BioSenic (Euronext Brussels and Paris: BIOS), the clinical stage company specializing in serious autoimmune and inflammatory diseases and cell repair, today announces the issuance of a key new patent entitled '*Use of metal ions to potentiate the therapeutic effects of arsenic'* (EP3972613) by the European Patent Office (EPO).

BioSenic has recently announced the publication of new data on the mechanism of action of arsenic trioxide (ATO) on 30 March 2023. This data has been published in peer-reviewed international journals in 2022 and 2023. As a result, BioSenic has developed a patent for its ATO combines with copper discoveries and potential applications, particularly in the fields of cancer and autoimmunity.

This specific new key patent issued by the EPO continues BioSenic's Group intellectual portfolio strategy involving further patent applications in other regions. These patents will accompany the implementation by BioSenic of international clinical trials in pathologies with clear unmet medical needs. These clinical trials will support BioSenic's aim of generating clinical data to support further market access approvals.

"BioSenic's new EPO patent, which has been granted for the 27 European countries, opens new avenues for the treatment of diseases with clinical unmet medical need in the field of immunity. This patent involves two main areas of application. The first is in innate, adaptive and trained immunity, and the second is in oncology, where arsenic trioxide has already demonstrated results for patients with acute promyelocytic leukaemia. These diseases affect a significant percentage of the world's population, and autoimmune diseases in particular lead to chronic illnesses with, all too often, severe prognostics," **said François Rieger, PhD, Chairman and Chief Executive Officer of BioSenic.** *"By achieving further understanding of the multiple effects of arsenic combined with copper and associating this with a new intellectual property of BioSenic, we will now be able to advance innovative treatments to meet the needs of many patients with challenging diseases that lack medical support."*

The results recently generated by BioSenic and published in two scientifically renowned peer-reviewed international journals demonstrate the benefits of using a combination of arsenic trioxide and copper salts in preclinical models of autoimmune diseases. These diseases include chronic graft versus host disease (Frontiers in Immunology, 2022), and systemic sclerosis (Frontiers in Medicine, 2023). These results provide data to support the potential of this combination therapy will be translate by BioSenic into clinical trials.

The expected availability of an oral formulation that combines arsenic and copper puts BioSenic in a unique position to build on clinical successes in lupus and Graft versus Host Disease therapy. As a result, BioSenic will be able to continue clinical development with proprietary formulation containing less arsenic and that minimizes secondary side effects.

About BioSenic

BioSenic is a leading biotech company specializing in the development of clinical assets issued from: (i), the allogeneic cell therapy platform ALLOB and (ii) the Arsenic TriOxide (ATO) platform. Key target indications for the platforms include Graft versus Host Disease (GvHD), Systemic lupus erythematosus (SLE), Systemic Sclerosis (SSc) and high-risk tibial fractures.
Following the merger in October 2022, BioSenic combines the strategic positionings and strengths of Medsenic and Bone Therapeutics. The merger also enables Biosenic to add to its innovative cell therapy platform and strong IP for tissue repair protection with an entirely new arsenal of various anti-inflammatory and anti-autoimmune formulations using the immunomodulatory properties of 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 BioSenic technology platforms

BioSenic's technology is based on two main platforms:

1) *The allogeneic cell and gene therapy platform, developed by BioSenic with differentiated bone marrow sourced Mesenchymal Stromal Cells (MSCs) that can be stored at the point of use in hospitals. Its current investigational medicinal product, ALLOB, represents a unique, 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 after a single local injection. These cells are produced via a BioSenic's scalable manufacturing process. Following the CTA approval by regulatory authorities in Europe, BioSenic has initiated patient recruitment for the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB is currently being 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. The patient recruitment has been halted late February 2023 with 57 patients and the new rules permitted for statistical analysis should allow BioSenic to get the main results of this trial much earlier than anticipated in the original protocol, since they are expected by mid-2023.*
2) *The Arsenic TriOxide (ATO) platform developed by Medsenic. The immunomodulatory properties of ATO have demonstrated a double basic effect on cells of the immune system. The first effect is the increase of the cell oxidative stress in activated B, T or 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 pro-inflammatory cytokines involved in inflammatory or autoimmune cell pathways. One direct application is its use in onco-immunology to treat GvHD (Graft-versus-Host Disease) in its chronic, established stage. GvHD is one of the most common and clinically significant complications affecting long-term survival of allogeneic hematopoietic stem cell transplantation (allo-SCT). GvHD is primarily mediated by the transplanted immune system that can lead to severe multiorgan damage. Medsenic had been successful in a Phase II trial with its intravenous formulation, allowing arsenic trioxide to be granted an orphan drug designation status by FDA and EMA and is heading towards an international Phase III confirmatory study, with a new, IP protected, oral (OATO) formulation. Moderate to Severe forms of Systemic Lupus erythematosus (SLE) is another selected target, using the same oral formulation. ATO has shown good safety and significant clinical efficacy on several affected organs (skin, mucosae and the gastro-intestinal tract) in a Phase IIa study.*
   Systemic Sclerosis is, in addition, part of the clinical pipeline of BioSenic. Preclinical studies on pertinent animal models are positive. This gives good grounds to launch a Phase II clinical protocol for this serious disease that badly affects skin, lungs or vascularization, and with no actual current effective treatment.

In addition, BioSenic is developing an off-the-shelf next-generation improved viscosupplement, JTA-004, consisting of a unique combination of plasma proteins, hyaluronic acid - a natural component of knee synovial fluid, and a fast-acting analgesic. JTA-004 intends to provide added lubrication and protection to the cartilage of the arthritic joint and to alleviate osteoarthritic pain (OA) and inflammation. In March 2023, after the identification of new OA subtypes, BioSenic delivered a new post-hoc analysis of its Phase III JTA-004 trial on knee OA with positive action on the most severely affected patient population. This new post-hoc analysis changes the therapeutic profile of the molecule and potentially allows for the possibility of stratifying patients for a new, optimized Phase III clinical study. BioSenic, which does not intend to allocate R&D resources to support the clinical development of JTA-004 and will continue to focus its R&D activities on the development of its autoimmune (ATO) and cell therapy (ALLOB) platforms, is now seeking to collaborate with existing and potential partners to explore options for the future development of JTA-004 based on this new post-hoc analysis.

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