

BioSenic presents data on its new copper-arsenic trioxide combination for immunological disorders at the 25th International Conference on Redox Medicine

Combining arsenic and a metal ion decreases dosage needed for therapeutic effects in preclinical chronic graft-versus-host disease and systemic sclerosis models

Mont-Saint-Guibert, Belgium, June 20th 2023, 7.00am CET – **BioSenic** (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases and cell repair, will present the latest data on its arsenic trioxide (ATO) platform at the 25th International Conference on Redox Medicine 2023, held by Redox Medicine Society on June 21-23 in Paris, France. “Arsenic-Copper: A Double-Edged Sword for a Unique Double Benefit against Immunological Disorders”, will be presented by Dr. Carole Nicco, Chief Scientific Officer at BioSenic and newly elected President of Redox Medicine Society.

The presentation will focus on recent data for ATO, already FDA-approved as an injection to treat acute promyelocytic leukemia. In two recent publications, the company has demonstrated that adding copper improved ATO's reactive oxygen species (ROS)-mediated deletion of activated immune cells, among other action pathways. This increased efficacy could lead to an improved safety profile, and to new combination therapy approaches with advanced therapy medicinal products (ATMP). BioSenic is already evaluating an oral version of ATO (OATO) for systemic autoimmune indications, including an upcoming Phase III study in patients with chronic graft-versus-host disease following allogeneic hematopoietic stem cell transplant.

“The Redox Medicine Society conference has been running for 25 years, bringing together KOLs and renowned researchers from around the world to facilitate the translation of redox biology into medicine. The Redox Medicine Society congress is a source of fruitful encounters and scientific inspiration.” said Dr. Nicco. “We are excited to share our findings and hope that these data will inspire redox translational research to deliver more beneficial medicines.”

Dr Nicco will present “**Arsenic-Copper: A Double-Edged Sword for a Unique Double Benefit against Immunological Disorders**” as part of Session 3 on Redox Medicine in Health & Diseases: Innovations, & Strategies, at 9:20 a.m. CEST on Friday, June 23, 2023.

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 Biosenica 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/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 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 at the site of injury after a single local injection. These cells are produced via 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. Patient recruitment was halted in 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, 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 graft-versus-host disease (GvHD) 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 ATO 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. Another selected disease 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 a Phase IIa study. Another part of the BioSenic's clinical pipeline is systemic sclerosis. Preclinical studies on pertinent animal models have been positive. This gives good grounds to launch a Phase II clinical protocol for this serious disease that badly affects skin, lungs or vascularization, which has no 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 is designed to provide added lubrication and protection to the cartilage of the arthritic joint, and to alleviate osteoarthritic (OA) pain 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 analysis changed the therapeutic profile of the molecule and 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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