BioSenic identifies key biomarkers for cGvHD and submits patent to EPO

International patent to allow the development of an industrial biomarker analysis kit which could generate a turnover of 30 to 40 million euros globally

Mont-Saint-Guibert, Belgium, May 4th 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 submission of a key patent in the use of its ATO platform. The patent, entitled *Diagnostic method for detecting the pathological correlates of chronic graft-versus-host disease (cGvHD) using particular cytokine or chemokine biomarkers,* has been submitted at the European Patent Office desk (EPO). This patent covers the use of a new quantitative method to evaluate the impact of medications destined at changing the course of the chronic form of the Graft versus Host Disease (cGvHD).

In 2021, BioSenic successfully concluded a prospective national multicenter single-arm open-label Phase II study in 5 university hospital centers in France. In the trial, BioSenic treated 21 cGvHD patients with an intravenous formulation, known as Arscimed, of arsenic trioxide (ATO). BioSenic published positive safety and efficacy results in the international peer-reviewed journal Transplantation and Cellular Therapy. Subsequent analysis of patient serums now provides key data on the transition of cytokines/chemokines concentrations from an initial abnormal range of values to a normalized level, associated with reduced disease activity. Data of the post-hoc study are now available. These biomarkers will potentially help estimate the risk of developing the disease at early stages with measured levels of selected cytokines, and also to assess the therapeutic response to current standard of care or any new treatment.

"BioSenic's newly submitted patent will allow the company to accelerate the development and approval of its novel therapeutic agents in cGvHD. This patent covers quantitative research tools that are needed to evaluate short-term responses to treatments and to predict long-term clinical benefits," **said Prof. François Rieger, PhD, Chairman and Chief Executive Officer of BioSenic.** *"Regulatory agencies will be far more receptive to market approvals for treatment use of any active pharmacological ingredient if the means of quantitative monitoring of the assessment of the activity and direct staging of the disease are applicable. This patent adds to our extensive patent portfolio covering both of our therapeutic platforms. It will also be invaluable in our Phase 3 clinical trial using an oral formulation of ATO that is on target to start this year. Using this new disclosed quantitative method for the evaluation of disease activity will be a strong advantage to firmly establish the validity of any new experimental treatment*."

BioSenic's technology covered by the patent applies to a method and kit for diagnosing and monitoring cGvHD in an individual who has undergone an allogeneic hematopoietic stem cell transplantation. The patent describes biomarkers to be used to determine if the condition of a patient worsens or improves following standard or new treatments for cGvHD. This quantitative set of evaluations consists of determining the kinetics levels of selected, meaningful cytokines in an individual's blood sample. Such quantitative assessments of cGvHD can further guide clinical decisions and can help to analyze the outcome of endpoints in clinical trials. This industrial biomarker kit could generate a global turnover of 30 to 40 million euros as more than 15,000 patients are treated for cGvHD each year.

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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