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BioSenic provides support to forthcoming European conference on graft-versus-host disease

Mont-Saint-Guibert, Belgium, January 31, 2024, 7.00 am CEST – BioSenic (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases and cell therapy, today announces that it will attend and support the upcoming GvHGvL Meeting on 13-15 March, 2024 at University Hospital Regensburg, a biannual conference to lead scientific exchange around graft-versus-host disease (GvHD).

GvHD can result from transplanting bone marrow or stem cells from a donor to a patient. BioSenic is planning a Phase 3 study of its first-in-class oral arsenic trioxide (OATO) therapy in patients with chronic GvHD (cGvHD), a focus area for the company. The trial will test OATO as a first-line therapy for cGvHD and will begin enrolling the first of about 150 patients over three continents this year. After consulting several clinicians with extensive cGvHD experience in order to develop the protocol for its pivotal Phase 3 study in cGvHD, BioSenic decided to provide support for the biannual meeting, which is organized and hosted by the University Hospital Regensburg in Regensburg, Germany.

BioSenic's Chief Operating Officer and Chief Scientific Officer Carole Nicco, PhD, HDR and Chief Medical Officer Lieven Huysse, MD will attend the congress, focusing respectively on the biomarkers in cGvHD and fine-tuning of the outcome criteria for the upcoming cGvHD Phase 3 study. In addition, the pair will hold further discussions with international key opinion leaders in attendance.

Lieven Huysse, said: "*This is an excellent opportunity for us to meet important key opinion leaders in the GvHD field, as we finalize the protocol of our state-of-the-art clinical study. We understand how crucial it is to select the most appropriate criteria if we are to move toward a confirmatory outcome for the use of OATO as a first-line therapy, in addition to the standard of care. We are looking forward to learning from leaders in the GvHD field as we concentrate all our efforts on getting the Phase 3 trial up and running.*"

Carole Nicco adds: *" We have learned from ATO's mechanisms of action that it could be a very specific and novel type of immunomodulator. We now have a patent pending on biomarkers that allow us to follow the efficacy of treatment in cGvHD. We will focus on this aspect in the Phase 3 trial and ensure that we follow the effect of our treatment using the best possible biomarkers, which happens to be one of the very interesting sessions planned for GvH-GvL Meeting. I can't wait for detailed discussions with other experts in order to reach a consensus for the best-suited set of biomarkers we can add to the companion diagnostics we have already identified."*

François Rieger, President of the Board and CEO of BioSenic Group, concludes: *" Our Phase 2 study had promising results, including a 75% overall response rate in the full analysis set population and 82% in the per-protocol set patient population. At BioSenic, we believe that the international pivotal Phase 3 trial of our OATO treatment for cGvHD should provide a definitive indication of this new therapy's value, and clearly define the duration and dosage of the treatment. ATO has the distinct advantage of being safe and effective over short cycles of administration, reducing the occurrence of potential side effects, all of which were reversible. We expect the risk/benefit balance to be quite favorable."*

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®**, 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.*

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