BioSenic releases details of optimized administration approach ahead of planned Phase 3 trial of OATO for chronic graft-versus-host disease

- **New data builds on earlier findings from a post-hoc Phase 2 analysis that helped reposition BioSenic's oral arsenic trioxide (OATO) program for pivotal trials.**
- **Data to be submitted for peer-reviewed publication.**

Mont-Saint-Guibert, Belgium, 12 March 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 the publication of an open-access article describing an optimized schedule for administration of oral arsenic trioxide (OATO) treatment for chronic graft-versus-host disease (cGvHD), based on an earlier post-hoc analysis of Phase 2 data. The schedule will play an important role in the protocol for BioSenic's forthcoming pivotal Phase 3 clinical trial.

GvHD is a common occurrence following allogeneic hematopoietic stem cell transplantation, used to treat a range of blood and immune diseases, including several leukaemias and lymphomas. Standard treatment begins with corticosteroids, with mixed outcomes, and those with a chronic form of GvHD may need to continue treatment for years, highlighting the clear unmet need for better treatment. BioSenic previously conducted a Phase 2 clinical trial of intravenous ATO in cGvHD treatment following stem cell transplant, with results showing that the first-line use of ATO and corticosteroids in patients with moderate to severe disease is associated with both a high clinical response rate and less need for corticosteroids.

Last year, BioSenic announced the results of an additional, observational post-hoc analysis of the full set of clinical data from the Phase 2 trial, improving the overall understanding of clinical response, safety (SAE/AE related to ATO) and cGVHD severity evolution after short cycle(s) of ATO treatment. It shows that the risk of loss of overall response over time is greater in patients who received only one cycle of ATO since they are in partial or complete remission at week 6 post-treatment compared to patients who received two cycles of second-line treatment. The use of 2 cycles of 4 weeks each, separated by a rest period of 4 weeks on ATO at 0.15mg/kg/day, should be optimal for the future treatment of cGvHD patients. The therapeutic schedule of the upcoming Phase 3 trial will be adapted thanks to a recent advance that allowed for an oral ATO formulation that can be taken at home.

François Rieger, PhD, Chairman and CEO of BioSenic, said: *"Our careful analysis of the previous Phase 2 trial clinical data, obtained using a short sequence of administration of ATO to patients affected by chronic graft versus host disease, provides additional guidance for optimizing dosage and treatment timing of ATO. We are now focused on finalizing the submission package of our Phase 3 trial using our new oral formulation for ATO, to further confirm the positive therapeutic effects revealed by our first trial on a limited cohort of patients with moderate-to-severe disease. We are committed to demonstrate the exceptional therapeutic effect of ATO, in line with all previous preclinical and clinical recent data obtained in the field of autoimmunity. It is now clear that the strongest industrial positioning for BioSenic aligns with the recently revealed therapeutic power of arsenic trioxide, the main asset promoted by our company."*

BioSenic is committed to exploiting the immune modulating potential of ATO in new ways for a range of diseases. In oncology, intravenous treatment with ATO has made acute promyelocytic leukaemia (APL) the most curable blood cancer since 2002[1,2]. The company is now introducing an oral formulation of ATO under an exclusive licensing agreement from its partner Phebra for use in a one-month cycle treatment, repeated twice, which will significantly improve patient quality of life and compliance while reducing healthcare costs. BioSenic aims to better address the unmet medical need in cGvHD with this oral, take-at-home formulation, proven in earlier studies on APL patients to be safe and bioavailable compared to an intravenous delivered formulation. In addition, the company is developing other formulations to expand its potential applications into other immune-related disease areas.

Online, "Best administration schedule of ATO for optimal efficacy and safety of ATO treatment in chronic Graft versus host disease," is available online at https://www.preprints.org/manuscript/202403.0645/v1.

[1]Treatment of acute promyelocytic leukemia with arsenic trioxide without ATRA and/or chemotherapy - A. Ghavamzadeh et al - Ann Oncol (IF: 32.98; Q1). 2006 Jan;17(1):131-4.

[2]Single-agent arsenic trioxide in the treatment of newly diagnosed acute promyelocytic leukemia: durable remissions with minimal toxicity- Vikram Mathews et al. - Blood (IF: 22.11; Q1) 2006 Apr 1;107(7):2627-32.

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 composite ATO 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 recent Phase 2b trial, to optimise the efficacy of ALLOB by determining the best timing for therapeutic intervention and seeking partners to continue the development of 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 selected osteoarthritic patients in support of any possible licensing.*

For further information, please contact:

BioSenic SA
François Rieger, PhD, CEO
Tel: +33 (0)671 73 31 59
investorrelations@biosenic.com

International Media Enquiries:
IB Communications
Michelle Boxall
Tel: +44 (0)20 8943 4685
michelle@ibcomms.agency

French Investor Enquiries:
Seitosei • Actifin
Ghislaine Gasparetto
Tel: +33 (0)1 56 88 11 22
ghislaine.gasparetto@seitosei-actifin.com

Michael Scholze
michael.scholze@seitosei-actifin.com