Press Release
Media Contacts:
IB Communications
Tel +44 (0)20 89434685
biosenic@ibcomms.agency

BioSenic provides update regarding current license agreement with Phebra

- **Maintenance of the license is now subject to the launch of the OATO Phase III before May 2024 instead of 31 May 2023**
- **Parties also currently negotiating a potential renegotiation of the other licensing terms**

Mont-Saint-Guibert, Belgium, May 29 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 amendment of the license agreement between its affiliate Medsenic SAS and Phebra Pty Ltd, the leading Australian developer, manufacturer and supplier of high quality and innovative pharmaceuticals.

In May 2021, Medsenic and Phebra entered into a license agreement and a marketing and supply agreement for the oral formulation of arsenic trioxide ("OATO") in the following indications: Graft Versus Host Disease ("GvHD"), Systemic Sclerosis ("SSc"), Systemic Lupus Erythematosus 151 ("SLE"), infectious diseases related to COVID-19 and CNS inflammatory diseases related to Multiple Sclerosis.

Under the license agreement, Medsenic agreed to commence a clinical study using Phebra OATO. If such study would not start before 31 May 2023, Phebra could terminate the license agreement unless the parties agree to postpone such date. The license agreement grant is now subject to Medsenic's ability to commence a clinical study using OATO before 31 May 2024.

In addition, BioSenic Group and Phebra are currently analyzing the possibility to extend the Medsenic Territories and the commercial terms thereof.

"We are particularly satisfied of the excellent degree of coordination between Phebra and Medsenic, aimed at delivering the clinical batches for entering into the realization of the expected Phase 3 trial of the oral medication, related to the previously agreed on exclusive license between Phebra and Medsenic," **said Prof. François Rieger, PhD, Chairman and Chief Executive Officer of BioSenic. "***Both recent technical advances for the oral ATO clinical supply and the newly agreed amendment to the original license will help render possible a quick FDA approval, through a necessary IND submission, followed by the expected activation of centers and patients recruitment."*

About Phebra
Phebra, an Australian owned manufacturer, is committed to providing skills development and employment opportunities in the fields of research and development and production of commercial products for both local and export markets. Phebra is an equal opportunity employer of more than 120 people and supports the health of Australians by supplying over 65 medicines in critical therapeutic areas. Together with manufacturing medicines, Phebra collaborates with hospitals in developing sought after therapeutic solutions. It partners with companies to bring critical medicines into Australia. Phebra also supplies and out-licences products globally across the Pacific region, Asia, Europe, Canada, South Americas and the Middle East.

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.