Press Release
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BioSenic appoints Lieven Huysse, MD, as Chief Medical Officer

Appointment to drive late-stage clinical development of BioSenic's cell therapy and autoimmune disease platforms

Mont-Saint-Guibert, Belgium, April 3, 2023 – BIOSENIC (Euronext Brussels and Paris: BIOS), the company specializing in serious autoimmune and inflammatory diseases and cell repair, today announces it has appointed Lieven Huysse, MD, as permanent Chief Medical Officer (CMO), effective 17 April 2023.

Lieven Huysse will succeed Michel Wurm's, MD, who was appointed as CMO ad interim to drive forward the development of BioSenic's platforms. Michel has been a key element in the development of Medsenic and BioSenic during the last 18 months.

Lieven will be responsible for continued progression of both BioSenic late-stage assets:

- The ALLOB MSC platform using cells with immune privilege, anti-inflammatory properties and the ability to differentiate into bone tissues when injected into the specific bone sites to be regenerated or repaired. The Phase 2b trial of ALLOB, a randomized, double-blind, placebo-controlled study in patients with high-risk tibial fractures, will report decisive key results in Q2 2023. Lieven will help progress this trial to conclusion. This includes overall responsibility for liaising with the CRO nominated for the trial and liaising with investigators in the thirty-five trial centers across seven EU countries.
- For the autoimmune ATO platform, Lieven will also be focused on the start of the Phase 3 trial in cGvHD, as well as the Phase 2b trials in systemic lupus, and systemic sclerosis.

"BioSenic is now driving hard to speed up clinical development across all our treatment platforms. We have now optimized statistical analysis and completed recruitment for our Phase 2b clinical trial with our allogeneic bone cell therapy product, ALLOB. For our lead API arsenic trioxide platform, designed to target serious inflammatory and autoimmune conditions, our Phase 3 trial in chronic Graft versus Host Disease is on track to start this year, and Phase 2b trials in two other indications, systemic lupus, and systemic sclerosis to start later on. We have also just announced we have gained more insight on the mechanism of action of ATO and optimized ideal formulations to maximize efficacy and minimize side effects for systemic sclerosis. In addition, we have re-evaluated the results of the Phase 3 trial of BioSenic's enhanced viscosupplement JTA-004 targeting knee osteoarthritis, opening up fresh clinical development options," said **Prof. François Rieger, President and CEO of BioSenic.** "As a result of these clinical progresses, this is an ideal time for us to appoint Lieven as CMO. His experience and expertise will be invaluable as we seek to bring therapies to patients suffering from a range of underserved conditions with few, if any, alternative therapeutic options. These next clinical developments will be key value creation milestones for BioSenic throughout 2023 and into 2024. In addition, these late-stage clinical progressions will enable BioSenic to start the process of engaging with industrial partners to co-develop late-stage clinical projects and to look at other targets of interest in autoimmune diseases and cancer. I would like to thank Michel for his invaluable and extensive contribution over the past months to continuing to push our pipeline of candidates."

Lieven has been selected as CMO for his extensive expertise in the biopharma and medical device industries. This includes the managing multi-center international clinical studies, including pre-market approval studies for submission to regulatory authorities including the US FDA, reimbursement authorities and Key Opinion Leaders management. He has gained over eight years of experience in immunology, as well as in the diabetes, allergy, cardiovascular and psychiatry sectors. He has 17 years of experience in the medical device sector with knee, hip and spine, as well as with trauma, cardiovascular and endovascular products. He has held senior leadership positions in a number of European headquarters, including in Belgium, Switzerland, Spain and the Netherlands. He has served as CMO for Anaconda Biomed S.L., senior director of medical affairs at Intrinsic Therapeutics, Inc., director of clinical and regulatory affairs at Wright Medical EMEA (now Microport®), medical director for Menarini Group, global brand medical manager for Switzerland-based UCB Farchim, manager clinical Affairs EMEA at Stryker Corp. and Medical Advisor EMEA at Janssen.

"BioSenic is now driving late-stage clinical development of two highly innovative platforms, and currently targeting four indications with its cell therapy and ATO platforms. BioSenic, after its merger, has brought together two teams that are cross-pollinating to rapidly advance this diverse pipeline through clinical development. As CMO, I will now be responsible for driving through clinical candidates that can impact a wide range of patients suffering from a variety of conditions and make a meaningful difference to the lives of a large number of patients," said Lieven Huysse, CMO, BioSenic. "These developments mean joining BioSenic as CMO is far too good an opportunity to miss. I will be able to make a significant contribution to further investigation of the medical characteristics and mechanisms of action of the therapies, and continue to expand BioSenic's pipeline of indications, and move the late-stage trials in order to bring us towards the market as quickly as possible."

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

BioSenic's technology is based on two main platforms:

- *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 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.*
- *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.