BioSenic appoints Michel Wurm, M.D. as Chief Medical Officer

Appointment to further integrate BioSenic's both cell therapy and autoimmune disease platforms under the responsibility of a new CMO and cross-pollinate the experiences of both teams to accelerate clinical progression

Mont-Saint-Guibert, Belgium, December 02, 2022, 7am CET – BIOSENIC (Euronext Brussels and Paris: BIOS), the company specializing in serious autoimmune /inflammatory diseases and cell repair, today announces it has appointed Michel Wurm, MD, as interim Chief Medical Officer (CMO), responsible for the development of both of BioSenic's cell therapy and autoimmune disease platforms.

Michel Wurm replaces Anne Leselbaum as interim CMO and as an independent consultant. His appointment will commence with immediate effect. Both Michel and Anne worked and collaborated closely together alongside the medical and scientific teams throughout the processes of the merger between Bone Therapeutics and Medsenic, from when the discussions between the two companies started in May 2022. Michel will serve as CMO whilst BioSenic selects a permanent CMO from the list of candidates it is currently compiling. The new CMO will be selected for his/her expertise and experience in both autoimmunity and cell therapy.

"Now the merger is complete, BioSenic is fully focused on combining its clinical development pipelines from its cell therapy and autoimmune platforms. Michel's experience working within the clinical development team throughout the merger makes him the ideal candidate to drive the cell therapy platform ALLOB to the end of its phase IIb trial and start the phase III trial for our autoimmune platform, the following successful conclusion of the previous phase II trial. His years of expertise both in phase II and III clinical trials will be critical in this period for BioSenic," **said Prof. François Rieger, President and CEO of BioSenic.** *"Michel's experience means he will be best placed to prepare BioSenic to take full advantage of the results of the ALLOB phase IIb trial following completion, as well as conduct the most thorough preparation of the phase III trial for our autoimmune platform. These clinical developments will be key value creation milestones for BioSenic in the first half of 2023. This late-stage clinical progression will enable BioSenic to start the process of engaging with industrial partners to co-develop late-stage clinical projects and to look at other segments of interest in autoimmune diseases and cancer. I would like to thank Anne Leselbaum for her dedicated efforts during the merger until its completion."*

Michel has been selected as interim CMO primarily for his previous achievements for MedSenic. He has acquired considerable knowledge of clinical development, specifically in phase II and III. In Michel's career, he has designed and managed over 50 international phase II and III clinical studies and has extensive experience in working within clinical guidelines for, and interacting with regulatory agencies including the FDA and EMA. Michel has also acquired experience in a number of therapeutic target areas including cardiovascular diseases, inflammation and auto-immunity. Michel has also gained wider expertise in innovative drug development, including launching start-ups, filing patents, and raising funds for both private and public companies. Michel wrote the French adaption of 'The Investigator's Guide to Clinical Research', a manual for investigators and health professionals involved in conducting clinical research, investigator financial disclosure, noncompliance issues, the FDA audit process and data collection technologies.

As Michel has been instrumental in bringing together the clinical pipelines of Bone Therapeutics and Medsenic during the merger process, he has gained full working knowledge of the current clinical progress of the cell therapy platform ALLOB and has extensive working knowledge of the autoimmune platform using arsenic trioxide (ATO), and specifically its clinical development in cGvHD (chronic Graft vs Host Disease).

Michel will be immediately responsible for continued progression of both BioSenic 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 IIb trial of ALLOB, a randomized, double-blind, placebo-controlled study in patients with high-risk tibial fractures, is still ongoing and set to report important interim results in H1 2023. Michel will progress this trial to the intermediary analysis stage. 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 using ATO, Michel will also be focused on the start of the phase III trial in cGvHD, and will oversee the commencement of recruitment for the trial in a US center, to be selected shortly.

"BioSenic, through its merger, has acquired two platforms in cell therapy and autoimmune diseases. This has created an opportunity to cross-pollinate the experiences of both teams to drive through clinical development on our varied pipeline quickly. As CMO, I will now be responsible for driving through clinical candidates that can affect a wide spread of patients suffering from a range of conditions and make a meaningful difference to the lives of large numbers of patients," **said Michel Wurm MD, CMO, BioSenic**. *"A successful conclusion of the phase IIb trial for ALLOB and the start of the phase III trial for the autoimmune platform will be major milestones for BioSenic as well. This will include further investigation of the medical characteristics and mechanisms of action of the therapies. I will be determined to enable BioSenic to recruit and progress this trial quickly and reduce analysis time and increase the clarity of results. This will move 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 platforms

BioSenic's technology is based on:

1) *The allogeneic cell and gene therapy platform, developed by Bone Therapeutics 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. These cells are produced via a proprietary BioSenic scalable manufacturing process. Following the CTA approval by regulatory authorities in Europe, the Company has initiated patient recruitment for the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB continues to be evaluated for other orthopedic indications including spinal fusion, osteotomy, maxillofacial and dental, and should be of value in new indications when cells will be further adapted or transformed with additional targeting properties.*
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.

For further information, please contact:

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

For Belgian Media and Investor Enquiries:
Bepublic
Bert Bouserie
Tel: +32 (0)488 40 44 77
bert.bouserie@bepublicgroup.be

For International Media Enquiries:
IB Communications
Neil Hunter / Michelle Boxall
Tel: +44 (0)20 8943 4685
neil.hunter@ibcomms.agency / michelle@ibcomms.agency

For French Media Enquiries:
NewCap Media
Annie-Florence Loyer
Tel: +33 (0)1 44 71 00 12
afloyer@newcap.fr

For French Investor Enquiries:
Seitosei Actifin
Ghislaine Gasparetto
Tel: +33 (0)1 56 88 11 22
ggasparetto@actifin.fr