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BioSenic provides financial update

Launch of negotiation with main creditors

Agreement with Global Tech Opportunities (GTO) to secure short term financing

Mont-Saint-Guibert, Belgium, June 30, 2023, 7.00 am CEST – BIOSENIC (Euronext Brussels and Paris: BIOS), the innovative company addressing unmet medical needs in the areas of innate immunity, inflammation and organ/function repair, today provides a financial update.

BioSenic has obtained an official appointment of Yves Brulard to reach a negotiated agreement with certain main creditors to preserve the value of BioSenic for the benefit of all stakeholders. This will enable BioSenic to find the optimal route to continue delivering therapies to patients as quickly as possible. Confidential negotiations with certain main creditors are ongoing. The Company will provide regular updates on the evolution of the discussions.

BioSenic today also enters into an agreement with the ABO Securities subsidiary, Global Tech Opportunities 15, to secure short term financing on the basis of the existing convertible bond program. Subject to the terms and conditions of the agreement, BioSenic shall be entitled to draw down three tranches of each EUR 0.3 million in June, July and August under the existing convertible bond program, for an aggregate principal amount of EUR 0.9 million. The parties will discuss how to draw down the remaining EUR 600,000 of the existing program and have initiated discussions with a view to a possible renewal of the program. BioSenic is currently preparing a fundraising to be organized in Q3/Q4 2023 to initiate the Phase III clinical trial in chronic graft versus host disease (cGVHD) in Q1 2024.

With the short-term financing agreement and the current renegotiation of potential terms with main creditors, BioSenic anticipates having sufficient cash to carry out its business objectives during such process.

"I would like to thank ABO for the support it has provided and the institutional creditors for their support during this strategic period," **said Prof. François Rieger, PhD, Chairman and Chief Executive Officer of BioSenic.** *"The reorganization of BioSenic and the revaluation of its core assets has now been carefully implemented, eight months after the successful reverse merger of Medsenic and Bone Therapeutics to form BioSenic. The financial restructuring of the main debt is underway. This will put the company on a firmer financial footing and increase its attractiveness to investors. BioSenic's primary current goal is to devote full financial resources to the development of our lead treatment program targeting cGVHD. The initial task will be to confirm previous results on the therapeutic value of an arsenic salt in its oral formulation. Using the 505(b)(2) FDA pathway, these results will lead to other indications, either in autoimmunity or later in cancer."*

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 had initiated patient recruitment for the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB was 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 allowed BioSenic to get the main results of this trial much earlier than anticipated in the original protocol, by this mid-June 2023. In June 2023, BioSenic decided to suspend its interventional trial on fracture healing using ALLOB, following negative results obtained for the primary endpoint in the exploratory Phase IIb clinical trial with ALLOB IIb, which focused on safety and treatment timing efficacy.*

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 also, 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 a next-generation, off-the-shelf, enhanced viscosupplement, JTA, consisting of a unique combination of plasma proteins, hyaluronic acid (a natural component of synovial fluid in the knee) and a third active component. JTA or some derivatives intend 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 drastically changes the therapeutic profile of the combined components and allows for better patient targeting in new clinical developments. The company, which does not intend to allocate R&D resources to support the clinical development of JTA-004 itself will focus its R&D activities on the development of its autoimmune (ATO) platform.

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