Press Release
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BioSenic reacquires global IP rights and provides an update on JTA-004 development

BioSenic plans to further develop its program on an active injectable viscosupplement JTA, combining anti-pain and anti-inflammatory characteristics on a subtype of knee osteoarthritis.

Mont-Saint-Guibert, Belgium, May 17th, 2023 – BioSenic (Euronext Brussels and Paris: BIOS), the clinical stage company specializing in serious autoimmune and inflammatory diseases and cell repair, today announces an update to its future plans for clinical development of BioSenic's enhanced viscosupplement JTA. This includes BioSenic reacquiring intellectual property rights for the therapy.

BioSenic announced in March 2023 that it had it has re-evaluated the results of its Phase III trial of its enhanced viscosupplement JTA-004 targeting knee osteoarthritis (OA). The original results from this trial were released on August 2021. The multicenter, randomized, double-blind, placebo- and active-controlled Phase III study was conducted in 7 European countries and Hong Kong and included a total of 743 patients. The study did not meet the primary and consequently the key secondary endpoints, despite JTA's favorable safety profile.

In March 2022, a peer-reviewed paper formally identified three subtypes of OA, including one subtype of patients with more severe symptoms and inflammation. The recent post-hoc analysis conducted by BioSenic revealed that there were critical clinical confounding factors explaining the lack of discrimination among the general population of patients recruited for knee osteoarthritis (KOA): first, a placebo treatment with possible positive effects and second, the lack of stratification between patient subtypes. This allowed BioSenic to review all the data from the Phase III JTA-004 trial in early 2023. BioSenic used a statistical analysis specialist to study the results of the Phase III JTA-004 trial, particularly in the subset of patients with the most painful and inflammatory form of OA, representing about one-third of the total patients. The post-hoc results showed a pain-relieving effect of a single injection of JTA-004 a composition of three elements (hyaluronic acid, plasma proteins and clonidine). This benefit is not only superior to placebo but also to the active comparator.

This new in-depth analysis now enables BioSenic to recall the intellectual property rights to JTA, which were transferred to the Walloon Region in Belgium, with the reset of the initial financial agreement between both parties. BioSenic is already looking for an industry partner to submit its results to the regulatory bodies in order to find the best and fastest way to obtain a Marketing Authorization (MA). This partnership will jointly conduct a small-scale additional Phase III trial targeting the most severe form of knee OA, prior to the MA with global regulators. The Marketing Authorization Application (MAA) could be submitted as soon as three years after the start of the Phase III trial, and as a result JTA could reach the market in 2027.

"As a result of significant advances in medical knowledge of knee osteoarthritis*, BioSenic is now able to stratify previous clinical results and identify a specific subtype of the disease that can clearly benefit from the administration of a single injection of JTA. It has also been identified that the benefits of JTA to the subset of patients involves greater benefit than currently available therapies on the market, including Synvisc one, made of hyaluronic acid,"* **said Prof. François Rieger, PhD, Chairman and Chief Executive Officer of BioSenic.** *"As a result, BioSenic will be looking to make JTA available to the patients heavily affected by severe KOA as quickly as possible. This is going to be one of the additional new projects of BioSenic, bringing a strong diversification and new perspectives for BioSenic's pipeline of clinical indications."*

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.