PRESS RELEASE 25/01/2024

BioSenic presents new Phase 3 data on JTA-004 to treat severe osteoarthritis pain at the 2024 OARSI World Congress

Using a recently published approach to stratify patients with knee osteoarthritis, an external post hoc analysis of Phase 3 data showed JTA-004 is safe and efficient for treating pain symptoms in the most severely affected patients.

Mont-Saint-Guibert, Belgium, January 25 2024, 7.00 am CET – BioSenic (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases and cell therapy, will for the first time share post hoc data on its late-clinical asset JTA-004 at the Osteoarthritis Research Society International (OARSI) World Congress 2024. The post hoc analysis of a Phase 3 study found that a single injection of JTA-004 was safe and efficacious for patients with a newly characterized severe inflammatory subtype of knee osteoarthritis (OA). The data will be presented by Yves Henrotin, Ph.D, a professor at University of Liège in Belgium (musculoSKeletal Innovative research Lab, mSKIL), Center for Interdisciplinary Research on Medicine, CIRM), as well as Founder and the Chairman of the Board of Artialis, which performed the analysis.

JTA-004 is an innovative intra-articular viscosupplement treatment for knee OA, composed of hyaluronic acid, plasmatic proteins, and clonidine. The post-hoc analysis addresses different subpopulations of OA patients in the data of a Phase 3 trial (KOA-2) completed in 2019. The trial was intended to demonstrate that treatment with JTA-004 leads to a reduction in knee pain intensity compared to saline solution or Synvisc-One®, three months after injection, in subjects suffering from symptomatic knee OA.

The initial results in a broad pool including patients with several subtypes were inconclusive. However, BioSenic was inspired to reevaluate the previous data following the publication of a study[1] that identified biomarkers to stratify OA phenotypes, including a disease subtype characterized by systemic inflammation and the most severe symptoms. The conclusion of the post hoc analysis is that JTA-004 is safe and effective for successfully treating symptoms in this inflammatory-driven subgroup.

François Rieger, Ph.D, President of the Board and CEO of the BioSenic Group, said: *"We thank Prof. Henrotin, a renowned specialist, and his team of biostatisticians for this collaboration. This new, detailed analysis demonstrates the positive therapeutic effect of JTA-004 in severe OA, and it will enable a more specific approach to the unsolved problem of efficient pharmacological treatment of osteoarthritis pain."*

"*OARSI is dedicated solely to advancing OA research. It brings together KOLs and renowned researchers from around the world to facilitate the translation of knowledge about OA, a debilitating disease that affects about 528 million people worldwide and rising sharply. With more than 30 years of experience serving the OA community, OARSI provides the necessary framework, expert resources, and support for its international members to address the challenges of OA so that the knowledge gained can ultimately be used to improve patient care and outcomes,*" **said Carole Nicco, Ph.D, BioSenic Chief Scientific Officer and Chief Operating Officer**. "*We are pleased to share our findings at the Congress and hope that these data will support the further evaluation of our viscosupplement, which has all the characteristics to treat severe inflammatory OA and address an unmet medical need*."

BioSenic recently filed an additional patent application to support further development of JTA-004 for severe OA.

"A single intra-articular injection of JTA-004 is safe and efficient for treating symptoms in the most severely affected knee osteoarthritis (OA) patients – a multicenter, randomized, double-blind, placebo-and active-treatment controlled phase 3 clinical trial" will be presented at OARSI World Congress 2024, held April 18-21 in Vienna, Austria.

[1] Angelini F, et al. Ann Rheum Dis Feb 2022

About BioSenic

BioSenic is a biotech company specializing in the clinical development of autoimmune disease therapies. Following a reverse merger in October 2022, BioSenic combined its strategic positioning, key strengths and strong IP to develop products along two tracks, separately and in combination. The first platform leverages immunomodulatory properties of arsenic trioxide (ATO) for an entirely new arsenal of formulations, including oral delivery (OATO), for anti-inflammatory and anti-autoimmune indications such as chronic graft-versus-host disease (cGvHD), systemic lupus erythematosus (SLE) and systemic sclerosis (SSc). In parallel, BioSenic develops innovative products through a second platform that includes cell therapies and strong IP

protection for tissue repair technologies.

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's technology platforms

*The **ATO platform** has immunomodulatory properties with fundamental effects on the activated cells of the immune system. One direct application is its use in autoimmunity to treat in its chronic, established stage. Chronic GvHD is one of the most common and clinically significant complications affecting long-term survival of allogeneic hematopoietic stem cell transplantation (allo-HSCT), a curative treatment for patients with serious blood diseases, including cancers.*

*BioSenic's intravenous ATO formulation, **Arscimed®**, has orphan drug designation status by FDA and EMA, and it has shown good safety and significant clinical efficacy for skin, mucosae, and the gastrointestinal tract in an early Phase 2a study. The company is planning a confirmatory international Phase 3 study with its oral ATO (**OATO**) formulation. OATO will also target moderate-to-severe forms of SLE. BioSenic is also developing a new IP-protected OATO formulation for the treatment of SSc, a serious chronic disease that affects skin, lungs or vascularization, and has no current effective treatment. Preclinical studies on pertinent animal models support the launch of a Phase 2 clinical trial.*

***ALLOB** is an allogeneic cell therapy platform made of differentiated, bone marrow-sourced mesenchymal stromal cells (MSCs), which can be stored at the point-of-use in hospitals. ALLOB represents a unique and proprietary approach to organ repair, and specifically to bone regeneration, by turning undifferentiated MSCs from healthy donors into bone-forming cells at the site of injury. BioSenic is studying the results of a Phase 2 trial to optimise the efficacy of ALLOB by determining the best timing for therapeutic intervention and seeking partners to continue the development of the promising underlying therapy strategies.*

*The company is also exploring partnerships at all levels for its **JTA-004** viscosupplement for a severe inflammatory subtype of osteoarthritis, following a positive post hoc analysis of Phase 3 data demonstrating safety and efficacy in support of this licensing.*

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