PRESS RELEASE – INSIDE INFORMATION | 23/01/2024

BioSenic files for additional patent protection following new clinical evidence of efficacy for JTA-004 in osteoarthritis

Following a post-hoc analysis of a Phase 3 trial demonstrating pain relief in patients with severe knee osteoarthritis, Biosenic applied for an international patent to support the newly focused indication of JTA-004.

Mont-Saint-Guibert, Belgium, January 23, 2024, 7.00am CET – BioSenic (Euronext Brussels and Paris: BIOS), the clinical-stage company focused on serious autoimmune and inflammatory diseases and cell therapy, today announces the filing of a U.S. patent for JTA-004, a viscosupplement in late-stage clinical development, following new evidence of its efficacy in a recently defined subtype of osteoarthritis (OA).

There are several types of OA. In 2022, outside investigators published[i] findings that defined three subtypes based on biomarkers – including a severe form marked by high levels of pain, of certain biomarkers and persistent and progressive inflammation. Using this new approach to stratifying disease, BioSenic commissioned a post hoc analysis of a phase 3 trial for JTA-004 that had showed inconclusive results for patients with knee OA. By instead focusing on patients in their study with the severe inflammatory subtype, the analysis detected pain-relieving efficacy superior to both placebo and the active comparator.

Given the promising new findings, BioSenic now intends to expand patent protection for "Hyaluronic acid-based compositions and related methods for use in the treatment of osteoarthritis in specifically selected subjects." The rights were initially acquired from Bone Therapeutics following a reverse merger with Medsenic SAS to form BioSenic. As BioSenic develops a new clinical plan, this position will support steps toward commercializing JTA-004 for patients experiencing severe pain from knee OA.

JTA-004 differs from other hyaluronic acid-based products for OA in its inclusion of clonidine, an alpha-2 adrenergic inhibitor, as an active pharmacological component. Its analgesic properties have been known for decades, and more recent data has demonstrated prolonged local anti-inflammatory activity, as well as a normalizing effect on cell differentiation of chondrocytes. New findings published[ii] this month in *Nature* further connect chondrocytes to degeneration in knee OA, providing further potential explanation for JTA-004's positive clinical results in reducing symptoms of pain and inflammation in severe cases.

Prof. François Rieger, PhD, Chairman and Chief Executive Officer of BioSenic said: *"Given the exciting new findings in knee osteoarthritis, it is time to build on previous efforts to develop JTA-004 to control the most severe subtype of progressive knee osteoarthritis. As further clinical work is needed to fully establish the significant benefits expected from JTA-004, our IP position will provide significant protection as we explore partnerships to bring this important asset to a very large pharmacological market. We are dedicated to improving the lives of millions of patients continue to suffer from this often-debilitating disease."*

[i] Angelini F, et al. Ann Rheum Dis Feb 2022
[ii] Fu W, et al. Nature Jan 2024

About BioSenic

BioSenic is a biotech company specializing in the development of clinical assets issued from: (i) the arsenic trioxide (ATO) platform (with key target indications including Graft-versus-Host Disease (GvHD), systemic lupus erythematosus (SLE) and systemic sclerosis (SSc) and (ii), the development of innovative products to meet unmet needs in immune and autoimmune diseases. Following a reverse merger in October 2022, BioSenic combined its strategic positioning and key strengths to develop, separately and in combination, an entirely new arsenal of various anti-inflammatory and anti-autoimmune formulations using the immunomodulatory properties of ATO/oral ATO (OATO) with its innovative cell therapy platform and strong IP for tissue repair protection.

BioSenic is based in the Louvain-la-Neuve Science Park in Mont-Saint-Guibert, Belgium. Further information is available on the website at http://www.biosenic.com.

About BioSenic technology platforms

1) *The ATO platform has immunomodulatory properties with fundamental effects on the activated cells of the immune system. One direct application is its use in onco-immunology to treat GvHD (Graft-versus-Host Disease) in its chronic, established stage. cGvHD is one of the most common and clinically significant complications affecting long-term survival of allogeneic hematopoietic stem cell transplantation (allo-HSCT). BioSenic has been*

successful in a phase 2 trial with its intravenous formulation, which has orphan drug designation status by FDA and EMA. The company is heading towards an international phase 3 confirmatory study, with its new, IP-protected, OATO formulation. Another selected target is moderate-to-severe forms of systemic lupus erythematosus (SLE), using the same oral formulation. ATO has shown good safety and significant clinical efficacy on several affected organs (skin, mucosae and the gastrointestinal tract) in an early phase 2a study. Systemic sclerosis is also part of the clinical pipeline of BioSenic. This serious chronic disease badly affects skin, lungs or vascularization, and has no current effective treatment. Preclinical studies on pertinent animal models are positive, giving good grounds to launch a phase 2 clinical protocol.

2) *ALLOB, 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 stromal cells from healthy donors into bone-forming cells on the site of injury. After phase 2 clinical results with contradictory conclusions, BioSenic is now focusing on determining the best time to optimise the efficacy of ALLOB (between early or late treatment).*

The company is currently focusing its present R&D and clinical activities on a selective, accelerated development of its autoimmune (ATO/OATO) platform.

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