Press Release
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BioSenic delivers a new post-hoc analysis of its Phase III JTA-004 trial on knee osteo-arthritis with positive action on the most severely affected patient population

New analysis and formal identification of patient subsets open up further potential clinical development options for JTA-004

Mont-Saint-Guibert, Belgium, March 16, 2023 - BIOSENIC (Euronext Brussels and Paris: BIOS), the clinical stage company specializing in severe autoimmune/inflammatory diseases and cellular repair, announces today it has re-evaluated the results of its Phase III trial of its enhanced viscosupplement JTA-004 targeting knee osteoarthritis (OA).

BioSenic has obtained new statistical analysis results from the JTA-004 Phase III clinical trial data, released in 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-004's favorable safety profile. The final report was recently communicated to EudraCT (2019-000796-16).

In March 2022, in the journal 'Annals of the Rheumatic Diseases [1], a peer-reviewed paper formally identified three subtypes of OA, amongst which a subtype of OA patients with more severe symptoms and inflammation. A better understanding of disease stratification to classify patients with OA provided the input for this fresh, in-depth post hoc analysis. BioSenic has used the statistical analysis capabilities of Artialis to study the results of the Phase III JTA-004 trial in the subset of patients with the most painful and inflammatory form of OA. This allowed BioSenic to distinguish a group of patients, representing about one-third of the total patients, who show a pain-relieving effect of JTA-004 not only superior to placebo but also to the active comparator.

By identifying three subtypes of OA, amongst which a subtype of OA patients with more severe symptoms and inflammation, 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 Research and Development resources to support the clinical development of JTA-004 and will continue to focus its Research and Development 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.

Following the data of the Arthritis Foundation, OA is now recognized as a disease of the whole joint, affecting more than 32.5 million adults in the United States. By far the most common form of arthritis, OA does not yet have any drugs that can slow or modify the disease and only offers transitory relief of symptoms.

JTA-004 was designed as a next-generation of intra-articular injectable for the treatment of osteoarthritic pain in the knee. Consisting of a unique patented mix of plasma proteins, hyaluronic acid - a natural component of knee synovial fluid, and a fast-acting analgesic, JTA-004 was designed to provide added lubrication and protection to the cartilage of the arthritic joint and to alleviate OA pain.

"These new data demonstrate that JTA-004 may have the potential to provide an improved treatment for the most affected osteoarthritis patients that suffer from severe chronic pain and active, mostly progressive, inflammatory disease that is an under-served medical need," said **François Rieger, PhD, BioSenic's Chairman and CEO**. "*As a result, this opens up fresh options for BioSenic in addition to our current multiple autoimmune and cell therapy platforms. BioSenic will formally publish the fresh JTA-004 post hoc analysis results in a peer-reviewed paper in the second half of 2023 and will meanwhile explore multiple options for the further development of JTA, with potential partnership options and potential additional clinical development*."

[1] Angelini F, et al. Ann Rheum Dis 2022; 81:666–675. doi:10.1136/annrheumdis-2021-221763

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About BioSenic
BioSenic is a biotech company focused on (i) the development of innovative products to address high unmet needs in orthopedics and (ii) exploiting the possibilities offered by the therapeutic use of arsenic salts (mainly arsenic trioxide (ATO) for patients with autoimmune diseases. Key target indications for the platforms include Graft versus Host Disease (GvHD), Systemic lupus erythematosus (SLE), Systemic Sclerosis (SSc) and high-risk tibial fractures and other orthopedics indications, such as osteoarthritis, by combining new and tested, IP protected, techniques.
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 or 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:

- 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.
- 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.