Press Release
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BioSenic provides update on its autoimmune disease platform based on ATO (arsenic trioxide)

- **The autoimmune disease platform has completed a successful phase IIb trial targeting cGVHD (chronic Graft vs Host Disease), with a demonstrated efficacy of more than 75 percent**
- **Phase III is under preparation with expected accelerated examination by FDA**
- **Other indications should follow with wider market potential, including lupus and systemic sclerosis**

Mont-Saint-Guibert, Belgium, November 8, 2022 – BIOSENIC (Euronext Brussels and Paris: BIOS), the company specialized in serious autoimmune /inflammatory diseases and cell repair, today announces an update on its systemic autoimmune disease platform, originally designed by Medsenic. The update follows the announcement of the merger between Bone Therapeutics and Medsenic, and the listing on Euronext Brussels and Paris.

The BioSenic autoimmune platform has been constructed to target systemic autoimmune diseases using arsenic trioxide (ATO). This uses ATO's first-in-class mechanism of action as an active anti-inflammatory and immunomodulatory agent.

"Medsenic has developed its systemic autoimmune disease platform over a 12-year period to utilize the immunomodulation properties of arsenic trioxide. The properties of ATO as a small molecule are now well established," **said Prof. François Rieger, President and CEO of BioSenic**. "Following the merger, BioSenic is now developing controlled dosages and new formulations that are adapted to a significant number of important indications with unmet medical needs. We are looking to demonstrate that arsenic can potentially cure and save lives. Combining both our platforms, ALLOB from Bone Therapeutics and the new ATO platform by Medsenic, BioSenic will trigger key value creation milestones during the first half of 2023."

The unique efficacy of ATO to create long-lasting remission of a rare cancer condition, acute promyelocytic leukemia (APL), has been previously recognized by both FDA and EMA, with market approvals. BioSenic is now further actively clinically testing ATO as a main therapeutic asset for autoimmune diseases.

There are two mechanisms of action of arsenic trioxide for counteracting autoimmunity and inflammatory chronic diseases. The first is a significant increase in oxidative stress of activated immune cells leading to their death. The second inhibits the synthesis and/or release of proinflammatory cytokines. By combining the mechanisms of action, inflammation and active autoimmunity is drastic decreased. These immunomodulatory properties have important and long-lasting effects on the immune pathology in a number of autoimmune diseases. This has been extensively previously demonstrated in adequate animal models by Medsenic and other organizations.

BioSenic assets now comprise two platforms:

- The ALLOB MSC platform uses cells with immune privilege, anti-inflammatory properties and the ability to differentiate into bone tissues when injected into the specific bone sites to be regenerated or repaired. The phase IIb trial of ALLOB, a randomized, double-blind, placebo-controlled study in patients with high-risk tibial fractures, is still ongoing and set to report important interim results in H1 2023.
- The autoimmune disease platform using ATO has completed a phase IIb trial with positive results on safety and efficacy in 20 patients for cGVHD (chronic Graft vs Host Disease). A headline result for this corticosteroid-controlled trial was that patient's corticosteroids levels decreased as soon as six weeks following the start of the treatment with ATO, to reach minimal levels.

"Medsenic/BioSenic has recently completed a phase II study of Arsenic Trioxide in combination with corticosteroids as initial therapy for moderate-severe cGvHD. The promising response rates at six months justifies pursuing a phase III study, with a goal of broadening treatment options and reducing the overall morbidity of chronic GVHD in our transplant recipients," **said Prof. Corey Cutler**, medical director of the Stem Cell Transplantation Program at Boston's Dana Farber Cancer Institute and Harvard Medical School. Dr. Cutler's field of expertise is Graft Versus Host Disease.

The acquired clinical results and expected results from both platforms enable BioSenic to move forward into confirmatory phase III studies prior to Market Access procedures with regulatory agencies in US and Europe.

The phase III study of the autoimmune disease platform in cGvHD (Chronic Graft vs Host Disease) has been designed to reach the market as quickly as possible through the framework of an expedite 505b2 FDA regulatory pathway.

In addition to cGVHD, BioSenic is also preparing a randomized placebo-controlled phase IIb study with ATO in Systemic Lupus Erythematosus. This disease has a high prevalence - the worldwide prevalence of SLE can reach 108 per 100,000 inhabitants and its incidence 5.14 per 100,000 inhabitants per year (Tian et al, 2022, Ann Reum. Dis.). As a result, this disease is potentially a strategic target for BioSenic. In addition, promising preclinical data gathered by Medsenic has provided clinical data to support a phase II clinical trial with ATO targeting systemic sclerosis.

As a result, BioSenic expects key value creation milestones in H1 2023 with the interim phase IIb results of ALLOB and the start of the phase III study with ATO in cGvHD. BioSenic will start the process to engage with industrial partners to co-develop late-stage clinical projects and to look at other segments of interest in autoimmune diseases and cancer.

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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:

1. The allogeneic cell and gene therapy platform, developed by Bone Therapeutics 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. These cells are produced via a proprietary BioSenic scalable manufacturing process. Following the CTA approval by regulatory authorities in Europe, the Company has initiated patient recruitment for the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB continues to be evaluated for other orthopedic indications including spinal fusion, osteotomy, maxillofacial and dental, and should be of value in new indications when cells will be further adapted or transformed with additional targeting properties.
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.

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