PRESS RELEASE 20/03/2024

BioSenic presents successful preclinical data on its ATO medication for controlling key symptoms at the 2024 Systemic Sclerosis World Congress

- **Preclinical data in a transgenic mouse model shows beneficial effects on various clinical symptoms analogous to those observed in human systemic sclerosis.**
- **Findings may further support future clinical program.**

Mont-Saint-Guibert, Belgium, 20 March 2024, 7.00am CET – BioSenic (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases and cell therapy, presented the latest data on arsenic trioxide (ATO) for systemic sclerosis (SSc) at the 8th Systemic Sclerosis World Congress 2024. The data, obtained with the laboratory of Yannick Allanore, MD, Ph.D. from the Hospital Cochin, builds additional evidence for the use of ATO in multiple autoimmune conditions, as observed in various animal models and in recent pilot human clinical trials.

The scientific communication presented by Anne Cauvet and Pr. Allanore demonstrated the efficacy of ATO in Fra2 transgenic mice, which is used as a disease model of symptomatic SSc, a chronic autoimmune disease marked by multi-organ fibrosis. BioSenic has previously showed that ATO, a first-in-class specific immunomodulatory drug, has significant therapeutic action in humans, and the company is progressing several formulations for autoimmune diseases in clinical trials. The researchers further reported that ATO resulted in significant lung histological changes, a trend towards a decrease in various fibrotic makers and a strong reduction in vascular remodeling in the SSc mouse model. The mechanism of action of ATO appears to involve a marked counteraction of the immune activation characteristic of SSc, particularly Tcell involvement. These positive findings have encouraged BioSenic to continue studying ATO for potential use in SSc.

François Rieger, PhD, President of the Board and CEO of the BioSenic Group, said: *"Our past data, including several animal models of autoimmune diseases and recent Phase 2 trials in systemic lupus erythematosus and chronic graft-versus-host-disease, have shown the remarkable therapeutic benefits of BioSenic's liquid ATO solution for various autoimmune conditions with critical unmet medical needs. The more recent data for another serious autoimmune disease, systemic sclerosis, has given convincing preclinical evidence to support a Phase 2 trial for patients affected by this disease, which has no cure. The well-known safety of ATO's pharmacologically active ingredient mean derived products, including an oral formulation (OATO), may follow FDA's rapid 505(b)(2) regulatory path."*

Understanding the mechanisms of action of arsenic on target cells is essential to determine the best conditions of use and possibly optimal combinations with other drugs. The work of several research teams worldwide has highlighted the autoimmunity-regulating, anti-fibrotic and vascular remodeling properties of arsenic, with potential to treat the lethal lesions in SSc and other autoimmune pathologies.

Dr. Carole Nicco, BioSenic's CSO and COO, said: "We are pleased to highlight these results, which complement previous findings in another preclinical model of non-genetic but induced-SSc. All our preclinical data, taken together, provide a coherent picture of the significant therapeutic effect we can expect in human patients suffering from severe chronic autoimmune diseases with unmet medical needs."

The results were presented at the 8th Systemic Sclerosis World Congress last week in Prague, Czech Republic.

About BioSenic

BioSenic is a leading biotech company specializing in the development of clinical assets issued from its Medsenic's arsenic trioxide (ATO) platform. Key target indications for the autoimmune platform include graft-versus-host-disease (GvHD), systemic lupus erythematosus (SLE), and now systemic sclerosis (SSc).
Following the merger in October 2022, BioSenic combined the strategic positionings and strengths of Medsenic and Bone Therapeutics. The merger specifically enables Medsenic/Biosenic to develop an entirely new arsenal of various anti-inflammatory and anti-autoimmune formulations using the immunomodulatory properties of ATO/oral 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 the main Medsenic/BioSenic technology platform

*The **ATO platform** provides derived active products with immunomodulatory properties and 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).

Medsenic has been successful in a phase 2 trial with its intravenous formulation, ***Arscimed®****, 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). Systemic sclerosis is now full part of the clinical pipeline of Medsenic/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, using new immunomodulatory formulations of APIs recognized to be active on the immune system.*

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

Note: The allogeneic cell therapy platform-originating from the previous listed company Bone Therapeutics company, may be of renewed interest by using isolated and purified differentiated bone marrow Mesenchymal Stromal Cells (MSCs) as a starting material for further isolation of passive or active biological subcellular elements. Indeed, these cells may provide new subcellular vesicles potentially able to deliver a unique and proprietary approach to organ repair. BioSenic is now involved in determining new patentable approaches in this complex area of cell therapy.

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