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Medsenic, BioSenic's subsidiary, signed a new set of licensing and commercialization agreements with Phebra PTY Ltd.

The adapted supply and commercialization conditions to better achieve the development of the first oral formulation of arsenic trioxide for the treatment of cGvHD should provide the best chances for final market access.

Mont-Saint-Guibert, Belgium, July 2, 2024, 7.00am CEST – BIOSENIC (Euronext Brussels and Paris: BIOS), the clinical-stage company specializing in serious autoimmune and inflammatory diseases and cell therapy, and its subsidiary Medsenic SAS, today announce the signature of global licensing, supply and commercialization agreements with Phebra Pty Ltd. related to the adaptation of the License Agreement and the MDA signed earlier in May 2021, when Phebra became a minority shareholder in Medsenic SAS. The improved terms will make it more attractive for investors to participate in the financing of the upcoming Phase 3 trial of oral arsenic trioxide (OATO/ ArsciCor). This new licensing agreements between Medsenic SAS and Phebra Pty Ltd should facilitate the final steps of manufacturing, clinical confirmation of efficacy and subsequent commercialization of our oral arsenic drug in the field of chronic Graft versus Host Disease (cGvHD).

The existing License Agreement has been updated and provides a balanced set of terms best suited for the optimal drug manufacturing, clinical development and future commercialization of our oral arsenic trioxide medication (OATO/ArsciCor), all adapted to the sole indication of cGvHD. The license provides for a royalty on worldwide sales to Phebra, which simplifies and facilitates the terms and conditions for possible sublicensing to future external partners. In addition, under the license agreement, Phebra Pty Ltd. agrees that Medsenic SAS will have exclusive worldwide territorial rights for the use of OATO in GvHD. Commercial arrangements for other indications in the initial Licence Agreement remain unchanged.

With respect to the Supply and Commercialization Agreements, Phebra Pty Ltd. remains responsible for maintaining and updating the drug substance file to comply with the regulation of all active territories; of controlling the compliance with various regulatory authorities on ongoing supplier approval and compliance with Good Manufacturing Practices (GMP) requirements; of updating the drug master file of OATO; of managing the Contract Manufacturing Organization (CMO) and supply chain of the active pharmaceutical ingredient for the clinical release of the product; and of covering the regulatory and quality and GMP expenses.

In addition, Medsenic will have the right to establish an Australian entity to use the OATO patents for the cGvHD indication. The Australian entity will not commercially compete with Phebra Pty Ltd., particularly in the field of APL (acute promyelocytic leukemia) cancer treatment, by producing Medsenic's GvHD treatment in indication-specific packaging.

Prof. François Rieger, President of the Board and CEO of the BioSenic Group, said: *"Our collaboration and partnership with Phebra Pty Ltd. – a long term minority shareholder in our group – now leads us to an optimal set of agreements for our licensing and commercialization of the oral formulation of the API arsenic trioxide, OATO/ ArsciCor, which is believed to be favorable for of a smooth development and increased interest from new investors to help make our cGvHD project a success. Our goal is to provide patients with Graft versus Host Disease with a safe, effective and convenient therapeutic solution to treat and control, if not cure, this unmet medical need that occurs after the transplantation of a foreign, functional immune system following the elimination of cancer blood cells. The present radical improvement in the commercial agreement between Phebra Pty Ltd. and Medsenic should facilitate our task of implementing all the necessary funding for the few years of the cGvHD Phase 3 trial. It has already been stated that BioSenic needs a successful cGvHD lead development program: this is key to the company's success, although parallel efforts to develop new indications/therapeutic applications for innovative formulations of ATO can add very significant value."*

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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