Press Release
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BioSenic reaches agreement on a binding term sheet with Phebra PTY Ltd. with respect to the development of the first oral formulation of arsenic troxide for cGvHD treatment

A new binding term sheet has been signed to adapt the terms of two previous agreements under which Phebra granted Medsenic SAS, a subsidiary of BioSenic SA, an exclusive worldwide license agreement with a first marketing and distribution agreement (MDA) for OATO (oral arsenic trioxide) in the field of several targeted autoimmune diseases.

Mont-Saint-Guibert, Belgium, January 15, 2024 – 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 a binding term sheet with Phebra PTY Ltd. related to the adaptation of the License Agreement and the MDA signed in May 2021.

The initial License Agreement provided a commercialization agreement of 100 percent net profits for Medsenic SAS mainly in Europe and 55 percent net sales profit for Phebra PTY Ltd. in the rest of the world (including major markets such as the US, Canada, South America, Japan, South East Asia, China and Australia). In particular, the binding term sheet for the indication chronic Graft versus Host Disease (cGvHD) license now provides for a royalty payment of two percent on worldwide sales, which simplifies the conditions for offering sublicenses to new 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.

Regarding the MDA, Phebra PTY Ltd. agrees that the net profit allocation as stated in the initial MDA will be deleted for the sales revenues and profits generated from the sale of product, restricted to the indication cGvHD. Phebra PTY Ltd. also agrees to cover the costs of maintaining and updating the drug substance file to comply with the rules of all active territories; of controlling the compliance with various regulators on ongoing supplier approval and compliance to Good Manufacturing Practices (GMP) requirements; of updating the drug master file of OATO; of managing the Contract Manufacturing Organization (CMO) and supply chain from the active pharmaceutical ingredient to the clinical release of the product and of covering the regulatory and quality and GMP expenses. To take into account these costs for Phebra PTY Ltd., the cost-of-goods for the Medsenic final clinical OATO product will be increased by a mark-up of 20 percent.

In addition, Medsenic will have the right to establish an Australian entity to use the OATO patents for 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 having Medsenic's GvHD treatment produced in product-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 – leads us now to an agreement on our licensing and commercialization of the oral formulation of our lead product, ATO, much in favor of a smooth development and increased interest of new investors to help make our lead project a success. Our goal is to provide patients with Graft versus Host Disease with a critical therapeutic solution to treat and control, if not cure, this terrible, unmet medical need that occurs after the transplantation of a foreign, functional immune system following the elimination of cancer blood cells. The 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 is clear to BioSenic that a successful cGvHD development program is key to the company's success, although parallel efforts to develop new indications/therapeutic applications for innovative formulations of ATO, as well as optimizing/licensing other earlier technologies, essentially related to the cell repair platform using GMP mesenchymal stem cells, may add significant value.*

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 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.