PRESS RELEASE – INSIDE INFORMATION | 13/12/2024

Medsenic, a subsidiary of BioSenic, has signed a conditional letter of intent that could secure funding to cover part of the costs for its clinical trial on chronic graft-versus-host disease

Mont-Saint-Guibert, Belgium, 13 December 2024, 17:30 CET – BIOSENIC (Euronext Brussels and Paris : BIOS) announces the signing of a conditional letter of intent between Medsenic SAS and the Singapore based TrialCap Pte. Ltd. as a first step for a proposed financing arrangement through both debt and equity subscription. Final agreements are yet to be concluded between the two companies – which cannot be guaranteed at this stage – and, if finalized, the financing will among others remain contingent on the creation of an Australian subsidiary by Medsenic and the acquisition of additional resources necessary for carrying out the clinical trial. Medsenic is hence actively seeking the additional funding required to execute its program and initiate research, which is supported by the positive Phase 2 results and promising preclinical trials of its experimental drug in an oral formulation of its active ingredient, arsenic trioxide (ATO).

The potential financing agreement with TrialCap consists of (i) a loan of up to USD 8 million and (ii) an equity investment of USD 800,000, both of which conditional upon the establishment by Medsenic of an Australian subsidiary, Medsenic Australia, which would receive the funds, in addition to customary and specific conditions precedent to be specified in the definitive agreements. Commercial exploitation rights for the Asia-Pacific region would also be transferred to Medsenic Australia, while Medsenic SAS would retain all other rights, including those relating to the US market. Consequently, the initial planned investment with TrialCap at the BioSenic level will instead be executed at the level of the newly created Australian entity.

Regarding the loan, the lender would provide a principal term loan facility of up to USD 8 million, exclusively covering expenditures in Australia, and would be disbursed in tranches to finance up to 33% of the invoices from the Clinical Research Organization (CRO) that qualify as “Eligible Expenses” under the Australian Governments Research and Development Tax incentive Scheme. The facility will be structured as a loan note subscription agreement, with funds advanced directly to the clinical trial provider or Medsenic for relevant expenditures within the Phase 3 clinical study of oral arsenic trioxide (OATO) used as a first-line treatment for chronic graft-versus-host disease (cGvHD).

The proposed loan facility has a 7-year maturity from the first utilization date, an annual interest rate of SOFR plus 9.5% on disbursed amounts, and an upfront fee equal to 1.0% of the loan facility, payable with each drawdown.

Regarding the USD 800,000 equity investment in exchange for shares in Medsenic Australia, it will be disbursed in two tranches. The first tranche will be subscribed upon the meeting of all conditions precedent in respect of the definitive agreements, and the second once 30% of the loan facility has been utilized. The valuation has not yet been finalized. Medsenic Australia will also issue subscription rights equivalent to 20% of the total amounts drawn under the loan. These rights can be exercised once 30% of the loan facility has been utilized, with the exercise price equal to the subscription price of TrialCap's initial equity investment.

The execution of the above investment is subject to the following conditions, which have not yet been met: (i) satisfactory completion of a final due diligence by the lender, (ii) signing of definitive agreements and completion of conditions precedent in respect thereof, (iii) signing a contract with a CRO, (iv) establishing an Australian subsidiary, and (v) securing additional funds by Medsenic for a to-be-determined amount. Medsenic will bear the administrative costs of the letter of intent in the event of non-completion.

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.

For further information, please contact:

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