PRESS RELEASE 21/02/2023

BioSenic receives EUR 1 million from Pregene in accordance with terminated license agreement and expect new negotiations on common revisited grounds

Following the regaining of ALLOB global rights, BioSenic has received a final payment from Pregene linked to a previously achieved development milestone which has a significant impact on the financial fundamentals of BioSenic

BioSenic continues to conduct preliminary discussions with Pregene, Link Health and other potential partners to move forward with the development and commercialization of ALLOB in other geographies, including the US

Mont-Saint-Guibert, Belgium, February 21, 2023, 7am CET – BioSenic (Euronext Brussels and Paris: BIOS), the clinical stage company specializing in serious autoimmune / inflammatory diseases and cell repair, today announces it has received EUR 1 million (minus 6% taxes) from Pregene.

On 5 October 2020, BioSenic, Pregene and Link Health Pharma Co., Ltd ("**Link Health**") signed an exclusive license agreement for the manufacturing, clinical development and commercialization of ALLOB in China (including Hong Kong and Macau), Taiwan, Singapore, South Korea, and Thailand).

Following new legislation and regulatory internal rules Pregene informed BioSenic that they had to terminate their agreement, A statement from Pregene read: "*Our termination was necessitated by regulatory reasons. Due to the introduction of new laws and regulations, projects involving foreign human cells and related clinical trials will be prohibited in mainland China*."

As such, Pregene's participation in all activities ceased and all data and information related to ALLOB were transferred back to BioSenic.

As per the terminated license agreement, Pregene owed BioSenic a payment further to the achievement of development milestone. BioSenic has now received a payment of EUR 1 million (minus 6% taxes) from Pregene after achieving this milestone a few months ago and as a final payment for any remaining amount due.

ALLOB is being developed to improve the efficacy and safety of bone cell therapy, through the use of partially differentiated bone-forming cells derived from bone marrow mesenchymal stem cells of healthy adult donors. ALLOB is currently in Phase IIb trials for the treatment of patients with high-risk tibial fractures.

Although Chinese regulatory changes have halted establishment of ALLOB in the Chinese market, BioSenic has started preliminary discussions with Pregene, Link Health and other potential partners to move forward with the development and commercialization of ALLOB in other geographies, including the US. This expansion to other markets will enable the global potential of ALLOB to be realized, giving patients with bone disorders, worldwide access to life-changing bone cell therapy.

About BioSenic

BioSenic is a biotech company focused on (i) the development of innovative products to address high unmet needs in orthopedics and (ii) exploiting the possibilities offered by the therapeutic use of arsenic salts (mainly arsenic trioxide (ATO)) for patients with autoimmune diseases. 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 BioSenic 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 after a single local injection. These cells are produced via a BioSenic's scalable manufacturing process, and have already revealed their potential in a successful preliminary Phase 1/2a, following a single injection of ALLOB cells on the site of delayed-union fractures of long bones, including about one third of tibial fractures. Following a further CTA approval by regulatory authorities in Europe, BioSenic has initiated patient recruitment for the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB is currently being evaluated in a randomized, double-blind, placebo-controlled Phase IIb study in patients with high-risk tibial fractures, using its optimized production process.*
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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