Press Release
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BioSenic optimizes statistical analysis for its ongoing ALLOB Phase IIb study for high-risk tibial fractures, requiring fewer patients and completes patient recruitment

• Combination of advances in radiological assessments, new scientific insights in fracture healing and updated statistical analysis results in fewer patients needed for trial, and an earlier readout of relevant results, leading to significant reduction in trial time and costs
• Decisive statistical analysis results on primary endpoint now expected in Q2 2023
• ALLOB subscription rights to become exercisable if the trial RUST score difference is higher than 1.26 in the statistical analysis at month three after patient treatment

Mont-Saint-Guibert, Belgium, February 23, 2023 – BioSenic (Euronext Brussels and Paris: BIOS), the clinical stage company specializing in serious autoimmune / inflammatory diseases and cell repair, today announces a positive update to its ongoing Phase IIb clinical trial with its allogeneic bone cell therapy product, ALLOB.

BioSenic has utilized scientific advances and market knowledge in feature healing and scientific advances in radiology to initiate positive modifications to its Phase IIb ALLOB trial. As a result, the study has advanced from seeking pure basic clinical assessments to involving more quantitative data. This will allow for a superior significance analysis. This advance in the trial results assessment has been achieved through advances in radiographic procedures enabling increased clarity in statistical interpretation. As a result, BioSenic has decided, based on consultation with its external biostatistical advisors, that clinical investigators may now complete the recruitment of patients. The cohort of treated patients, amounting to 57 patients, is found to be sufficient for a sufficient level of significance.

"BioSenic's ALLOB represents a significant opportunity for clinical unmet medical needs in bone regeneration, namely difficult tibial fractures. These affect more than 300,000 patients per year in US and EU alone and can have a significant impact to the lives of those affected. As a result, there is a pressing demand to develop accelerated bone regeneration in these patients. The results of the modified Phase IIb clinical trial with our allogeneic bone cell therapy product will add to the positive results of the previous Phase I/IIa on delayed fractures, obtained and published after a recent successful open label, non-randomized study on long bones including tibia (NCT02020590*[1]*). These previous clinical results have positively demonstrated good tolerability, evidence of increased bone formation and other clinical benefits," said François Rieger, PhD, Chairman and Chief Executive Officer of BioSenic. "As a result of these modifications to the current Phase IIb clinical trial, BioSenic will be able to quickly deliver the results expected from the original protocol, supported by the regulatory agencies. These results will be sufficient to define the next steps for further clinical evaluations of ALLOB, which could include a Phase III clinical trial required for market approval submission to regulatory agencies."

Results from ALLOB Phase IIb trial shall now be made available three months after difficult fracture and infusion of the ALLOB cells in the wounded sites of the 57 patients recruited. BioSenic expects to deliver decisive key results from this Phase IIb trial in Q2, 2023. The updated statistical analysis plan replaces the primary endpoint which now evaluates the difference between the placebo group and the experimental, ALLOB group in function of its compounded score from radiographic data collected after three months of treatment.

BioSenic's new statistical analysis plan leads to a more objective scoring for judging the result of its innovative cell repair treatment. A RUST score difference higher than 1.26 will be considered statistically relevant. A quantitative evaluation of the progress of the healing status of each patient will be given on a scale of a RUST score between 4 (no union) and 12 (complete healing), through a careful radiographic evaluation by two independent specialists. BioSenic considers this new statistical analysis corresponds more appropriately to the general conditions of the trial, its overall timing and expected evaluation power. The actual cohort of patients is considered to be wide enough to reach significance for its new critical ALLOB efficacy primary endpoint.

The ALLOB Phase IIb trial will also gather results on specific clinical evaluation criteria (secondary endpoints) and safety aspects, in accordance with the original study protocol. Treated patients will

continue to be evaluated until full completion of the safety part of the study, as a follow-up of two years for each treated patient.

Further to the decision to end recruitment and proceed towards a full set of meaningful results, the ALLOB subscription rights shall become exercisable based on the results at month three after patient treatment, if the difference in the mean RUST scores between the placebo's arm patient population and the treated ALLOB population is found higher than 1.26 in the new statistical analysis on the effectively recruited 57 patients. The BioSenic Board adopts the view that the new exercise criteria does not reduce the global advantages granted to the ALLOB subscription rights holders. The updated ALLOB subscription rights terms and ALLOB subscription rights Q&A are available on https://www.biosenic.com/investors.

[1] NCT02020590 - https://clinicaltrials.gov/ct2/show/NCT02020590?term=NCT02020590&draw=2&rank=1

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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 an found d 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 theimmunomodulatory 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. Following the 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, after a successful first safety and efficacy study (Phase 1/2a) on fractured long bones, with late delayed union.
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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