BioSenic provides First Quarter 2023 Business Update

ALLOB Phase IIb topline results foreseen in July/August 2023

Ongoing discussions for key partnerships with lead clinical assets

Mont-Saint-Guibert, Belgium, May 22nd, 2023 7.00am CET – BioSenic (Euronext Brussels and Paris: BIOS), the clinical stage company specializing in serious autoimmune and inflammatory diseases and cell repair, today announces its business update for the first quarter, ended 31 March 2023.

Key highlights

- Strengthening of Executive Committee and Board of Directors with the appointments of Dr Carole Nicco as Chief Scientific Officer, Dr Lieven Huysse as Chief Medical Officer and Yves Sagot as Independent Director.
- In February 2023, BioSenic announced it received EUR 1 million from Pregene in accordance with the terminated license agreement.
- In February 2023, BioSenic announced an optimization its ongoing Phase IIb clinical trial with its allogeneic bone cell therapy product, ALLOB and completion of patient recruitment.
- In March 2023, BioSenic announced that it has used the statistical analysis capabilities of Artialis to study the results of the Phase III JTA-004 trial in the subset of patients with the most painful and inflammatory form of knee osteoarthritis (OA). This allows BioSenic to distinguish a group of patients, representing about one third of the total patients, who show a pain-relieving effect of JTA-004 not only superior to placebo but also to the active comparator. This new post-hoc analysis changes the therapeutic profile of the molecule and potentially allows for the possibility of stratifying patients for a new, optimized Phase III clinical study.
- In March 2023, BioSenic published new data providing additional details about the mechanism of action of its lead API arsenic trioxide (ATO) to prevent autoimmune diseases has now been published in a peer-reviewed paper (Frontiers in Immunology). This new data shows that combination of ATO with copper salts can allow BioSenic to work towards reducing the dosage of ATO in future trials overall and maintain efficacy. This new formulation data has been completed following pre-clinical activities and does not constitute data validated through clinical trial.
- In April 2023, BioSenic received a key European patent from EPO, for further therapeutic development in cancer, infectious and immune diseases. The patent covers the therapeutic use of a new composite formulation of anti-inflammatory compounds with unique advantages. This new formulation lowers the dosage of arsenic trioxide by combining it with copper salts to maintain therapeutic efficacy, with the potential of administration through multiple routes, including intravenous, oral and other novel routes of administration.
- In May 2023, BioSenic identified key biomarkers for cGvHD and submitted patent to EPO. The technology covered by the patent applies to a method and kit for diagnosing and monitoring cGvHD in an individual who has undergone an allogeneic hematopoietic stem cell transplantation. The patent describes biomarkers to be used to determine if the condition of a patient worsens or improves following standard or new treatments for cGvHD. This international patent could allow the development of an industrial biomarker analysis kit which could generate a turnover of 30 to 40 million euros globally.
- In May 2023, BioSenic announced it reacquired global IP rights for JTA-004 and provided update on JTA-004 development. BioSenic is looking for an industry partner to submit its results to the regulatory bodies in order to find the best and fastest way to obtain a Marketing Authorization (MA). This partnership will jointly conduct a small-scale additional Phase III trial targeting the most severe form of knee OA, prior to the MA with global regulators. The Marketing Authorization Application (MAA) could be submitted as soon as three years after the start of the Phase III trial, and as a result JTA could reach the market in 2027.

Financial highlights

- Net cash at the end of March 2023 amounted to €1.45 million [(1)].
- Disciplined cost and cash management will remain a key priority. The operating cash burn for the full year 2023 is in the range of €8-10 million and a financing cash burn of approximately EUR 1.7 million. The situation will be actively and closely monitored. BioSenic anticipates having sufficient cash to carry out its business objectives until end of June 2023, assuming (amongst other) issuance of the eighth tranche of the Convertible Bonds and the renegotiation of the terms of the ongoing loans that will otherwise fall due in June 2023.

Outlook for the remainder of 2023

- In the ongoing Phase IIb ALLOB clinical study in difficult tibial fractures, BioSenic expects to report topline results by July/August 2023. The company will provide updates subsequently.
- BioSenic has started preliminary discussions with Pregene, LinkHealth and other potential partners to reach an agreement for the development and commercialization of ALLOB.
- In March 2023, BioSenic has obtained new statistical analysis results from the JTA-004 Phase III clinical trial data. BioSenic, which does not intend to allocate R&D resources to support the clinical development of JTA-004, is seeking to collaborate with existing and potential partners to explore options for the future development of JTA-004 based on this new post-hoc analysis.
- The Medsenic Phase II clinical study with arsenic trioxide in the first-line treatment of cGvHD has been completed and provided positive results. A Phase III study with oral arsenic trioxide in the first-line treatment of cGvHD, for which Medsenic received positive pre-IND response from the FDA, is currently anticipated to start in 2023. A Phase IIa clinical trial for systemic lupus erythematosus ("SLE") had previously established safety for the patient and efficacy on the course of the autoimmune disease. Positive preclinical work gives good grounds for a Phase II clinical trial on systemic sclerosis ("SSc"). Phase IIb clinical trials for SLE and SSc are in the planning stage with the protocols for both studies being ready.
- BioSenic Group, however, expects to use the existing cash and the proceeds of anticipated future fundraisings (via shares or (convertible) bonds) in priority for achieving the Phase IIb clinical trial for ALLOB and for progressing the Phase III clinical trial in cGvHD. As a result, it will only be possible to start the SLE and SSc Phase IIb clinical trials if the BioSenic Group succeeds in concluding a strong partnership with a biopharmaceutical company or if it manages to successfully out-license some of its technology. The start of SLE and SSc Phase II clinical trials is therefore not envisioned before 2024.

[(1)] Unaudited numbers

About BioSenic

BioSenic is a leading biotech company specializing in the development of clinical assets issued from: (i), the allogeneic cell therapy platform ALLOB and (ii) the Arsenic TriOxide (ATO) platform. 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 two main platforms:

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. The patient recruitment has been halted late February 2023 with 57 patients and the new rules permitted for statistical analysis should allow BioSenic to get the main results of this trial much earlier than anticipated in the original protocol, since they are expected by mid-2023.*
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.

In addition, BioSenic is developing an off-the-shelf next-generation improved viscosupplement, JTA-004, consisting of a unique combination of plasma proteins, hyaluronic acid - a natural component of knee synovial fluid, and a fast-acting analgesic. JTA-004 intends to provide added lubrication and protection to the cartilage of the arthritic joint and to alleviate osteoarthritic pain (OA) and inflammation. In March 2023, after the identification of new OA subtypes, BioSenic delivered a new post-hoc analysis of its Phase III JTA-004 trial on knee OA with positive action on the most severely affected patient population. This new post-hoc analysis changes the therapeutic profile of the molecule and potentially allows for the possibility of stratifying patients for a new, optimized Phase III clinical study. BioSenic, which does not intend to allocate R&D resources to support the clinical development of JTA-004 and will continue to focus its R&D activities on the development of its autoimmune (ATO) and cell therapy (ALLOB) platforms, is now seeking to collaborate with existing and potential partners to explore options for the future development of JTA-004 based on this new post-hoc analysis.

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