

Bone Therapeutics to strategically focus on lead cell therapy product ALLOB

Strategic focus revised and fully focused on achieving topline results of the ALLOB Phase IIb study in tibial fractures.

Discussions for ALLOB global partnership still ongoing.

Board of Directors and Management exploring all strategic options to protect shareholder value.

Miguel Forte (CEO), Tony Ting (CSO), Stefanos Theoharis (CBO) and Lieve Creten (CFO) will transition to leave the company over the coming months.

Mont-Saint-Guibert, Belgium, 29 March 2022, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, today announces it is redefining its strategic priorities to concentrate specifically on the development of its most advanced clinical asset, the allogeneic cell therapy platform, ALLOB.

ALLOB is currently being evaluated in a randomized, double-blind, placebo-controlled Phase IIb study in patients with high-risk tibial fractures. Based on the positive results of the previous clinical studies of ALLOB undertaken by Bone Therapeutics and the extensive preclinical data set, Bone Therapeutics firmly believes that ALLOB has the highest potential of near-term value creation. Topline results of the Phase IIb trial are still anticipated in Q1 2023. However, a delay cannot be excluded.

In order to deliver the results from the Phase IIb clinical study, Bone Therapeutics has implemented a number of actions to reduce its cost base to enable completion of its Phase IIb study. As a result, Bone Therapeutics will focus its R&D activities to support the clinical development of ALLOB and all activities related to the development of the pre-clinical iMSCg platform as well as all other non ALLOB related activities, will be stopped.

In this context, some members of Bone Therapeutics' management team will transition to depart Bone Therapeutics in the coming months in alignment with the focus in activity. This includes Miguel Forte (CEO), Tony Ting (CSO), Stefanos Theoharis (CBO) and Lieve Creten (CFO). The CEO, Miguel Forte, will remain in function for the transition. In addition, all non-executive members of the Board of Directors have decided to suspend their compensation for the first quarter of 2022 and until further notice.

The ongoing completion of ALLOB Phase IIb study will be supervised by Anne Leselbaum, MD (Chief Medical Officer) and Anne-Sophie Lebrun, PhD (Chief Operation Officer).

The negotiations for ALLOB, with one of the current Bone Therapeutics Chinese partners, for the global rights agreement are still ongoing but are taking longer than anticipated. The potential completion of a final binding agreement has been delayed beyond the end of Q1 2022.

Subsequent to some preliminary contacts, the board of directors of Bone Therapeutics is currently examining various opportunities to combine certain activities within Bone Therapeutics, taking into account the interests of its shareholders and other stakeholders. Further announcements will be made in due course, if and when circumstances so allow or require.

About ALLOB

ALLOB is Bone Therapeutics' off-the-shelf allogeneic cell therapy platform consisting of human allogeneic bone-forming cells derived from cultured bone marrow mesenchymal stromal cells (MSC) from healthy adult donors. To address critical factors for the development and commercialization of cell therapy products, Bone Therapeutics has established a proprietary, optimized production process that improves consistency, scalability, cost effectiveness and ease of use of ALLOB. This optimized production process significantly increases the production yield, generating thousands of doses per bone marrow donation. Additionally, the final ALLOB product is cryopreserved, enabling easy shipment and the capability to be stored at the point of care for easy clinical use. The process will therefore substantially improve product quality, reduce overall production costs, simplify supply chain logistics, increase patient accessibility and facilitate global commercialization. The Company has implemented the optimized production process to produce clinical batches for the ongoing Phase IIb clinical trial in patients with difficult-to-heal tibial fractures.

About Bone Therapeutics

Bone Therapeutics is a leading biotech company focused on the development of innovative products to address high unmet needs in orthopedics and other diseases. Currently Bone Therapeutics is concentrating specifically on the development of its most advanced clinical asset, the allogeneic cell therapy platform, ALLOB.

Bone Therapeutics' core technology is based on its cutting-edge allogeneic cell and gene therapy platform with differentiated bone marrow sourced Mesenchymal Stromal Cells (MSCs) which can be stored at the point of use in the hospital. Its leading investigational medicinal product, ALLOB, represents a unique, proprietary approach to bone regeneration, which turns undifferentiated stromal cells from healthy donors into bone-forming cells. These cells are produced via the Bone Therapeutics' scalable manufacturing process. Following the CTA approval by regulatory authorities in Europe, the Company has initiated patient recruitment for the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB continues to be evaluated for other orthopedic indications including spinal fusion, osteotomy, maxillofacial and dental.

Bone Therapeutics' cell therapy products are manufactured to the highest GMP (Good Manufacturing Practices) standards and are protected by a broad IP (Intellectual Property) portfolio covering ten patent families as well as knowhow. The Company is based in the Louvain-la-Neuve Science Park in Mont-Saint-Guibert, Belgium. Further information is available at www.bonetherapeutics.com.

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