

Bone Therapeutics Provides First Quarter 2021 Business Update

Strong clinical progress especially in JTA-004 Phase III study thanks to high patient compliance and retention

Process development partnership and appointment of cell therapy expert Anthony Ting as CSO to further strengthen product pipeline

Gosselies, Belgium, 26 May 2021, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, today announces its business update for the first quarter, ended 31 March 2021.

“Bone Therapeutics has continued the strong momentum into 2021,” said Miguel Forte, MD, PhD, CEO of Bone Therapeutics. “Bone Therapeutics’ mid-late stage clinical programs continue to advance largely on schedule, including the Phase IIb trial of the allogenic cell therapy platform ALLOB in difficult-to-heal tibial fractures and the Phase III trial of the enhanced viscosupplement JTA-004 in knee osteoarthritic pain. Alongside this, Bone Therapeutics has strengthened its manufacturing and R&D capabilities by signing a process development partnership with Rigenrand. It has also appointed the industry veteran Tony Ting as our new Chief Scientific Officer. Building on these achievements, Bone Therapeutics will be able to continue significant clinical and commercial advancements as we move towards the topline data of our JTA-004 Phase III study; a potential key inflection point for Bone Therapeutics.”

Operational highlights

- Patient recruitment of the pivotal Phase III with the improved viscosupplement JTA-004 in patients with knee osteoarthritis was successfully completed in December 2020. Patients are currently being monitored in follow-up. Despite the effects of the pandemic, patient study compliance and retention remain high. As a result, Bone Therapeutics has

already achieved the minimum number of patients required for the assessment of the primary endpoint completing their three month follow up. The study is on schedule to have top line efficacy data available in Q3 2021 with continued monitoring until year end and full results available in 2022. Positive results in this study could allow Bone Therapeutics to submit a marketing authorization application as early as H1 2022 for the commercialization of its first product in Europe and additional territories in Asia.

- In January 2021, Bone Therapeutics initiated the treatment of patients in the Phase IIb study of its allogeneic cell therapy product, ALLOB, in patients with difficult tibial fractures. Early recruitment rates were very promising, though understandably, in March and April 2021 the rate of recruitment has slowed slightly due to pandemic-related factors, such as reduced site activities due to staff availability and number of patients due to less accidents. Bone Therapeutics has taken and will continue to take action to intensify the recruitment through site expansion, training, information, best practices sharing and close monitoring of progress. The initial result of these activities has already shown a positive impact on patient recruitment.
- Bone Therapeutics signed an initial agreement for a process development partnership with the mesenchymal stromal cell (MSC) specialist, Rigenerand. This first collaboration will focus on further developing and enhancing Bone Therapeutics' bone-forming cells with the potential to broaden therapeutic targets and explore new mechanisms of action with potential gene modifications for Bone Therapeutics' therapeutic portfolio.
- Bone Therapeutics appointed the stem cell therapy industry veteran, Anthony Ting, PhD, as Chief Scientific Officer. Dr. Ting will be responsible for Bone Therapeutics' research activities. His immediate focus will be leading the expansion of Bone Therapeutics' pipeline into new therapeutic indications, leveraging internal know-how and external collaborations on novel, specialized cell therapy products with enhanced efficacy, using differentiated and modified MSCs.

Financial highlights

- Net cash at the end of March 2021 amounted to €8.5 million ⁽¹⁾.
- Disciplined cost and cash management will remain a key priority. The net cash burn for the full year 2021 is expected to be in the range of €16-17 million, assuming normal operation as the effect of the ongoing COVID-19 epidemic cannot be excluded. Bone Therapeutics anticipates having sufficient cash to carry out its business objectives into November 2021. To further strengthen its cash position in the near term, the company is currently evaluating and working on different financing options and plans to raise new funds with a focus on non-dilutive funding strategies.

Outlook for the remainder of 2021

- Bone Therapeutics aims to report topline results for the 3-month primary endpoint and 6-month follow-up period in the third quarter of 2021 for its pivotal Phase III clinical study with JTA-004.
- For the ongoing Phase IIb ALLOB clinical study in difficult tibial fractures, Bone Therapeutics' clinical team, in partnership with the clinical research organization, has

instituted corrective measures to mitigate the impact of the pandemic. Given the early stage of the study conduct and recruitment together with successful initial mitigation actions, Bone Therapeutics does not at this time expect the slightly lower recruitment rate to have a material effect on the anticipated completion of recruitment in H1 2022 and the planned top line results date in H2 2022.

- Bone Therapeutics will continue to hold discussions with potential partners to explore business opportunities as JTA-004 is approaching the announcement of pivotal Phase III topline results and ALLOB is being evaluated in a double-blind, placebo-controlled, proof-of-concept Phase IIb study.
- Bone Therapeutics will continue its discussions with the US FDA (Food and Drug Administration) in preparation for the next steps in the clinical development of JTA-004 and ALLOB in the US.
- Bone Therapeutics plans to continue to expand its allogeneic differentiated MSC based cell therapy platform, beyond ALLOB, into other therapeutic indications.

(1) Unaudited

number

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. The Company has a diversified portfolio of cell and biologic therapies at different stages ranging from pre-clinical programs in immunomodulation to mid-to-late stage clinical development for orthopedic conditions, targeting markets with large unmet medical needs and limited innovation.

Bone Therapeutics is developing an off-the-shelf next-generation improved viscosupplement, JTA-004, which is currently in Phase III development for the treatment of pain in knee osteoarthritis. 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 and inflammation. Positive Phase IIb efficacy results in patients with knee osteoarthritis showed a statistically significant improvement in pain relief compared to a leading viscosupplement.

Bone Therapeutics' core technology is based on its cutting-edge allogeneic cell therapy platform with differentiated bone marrow sourced Mesenchymal Stromal Cells (MSCs) which can be stored at the point of use in the hospital. Currently in pre-clinical development, BT-20, the most recent product candidate from this technology, targets inflammatory conditions, while the 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 BioPark in Gosselies, Belgium. Further information is available at www.bonetherapeutics.com.

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