Bone Therapeutics Provides Third Quarter 2021 Business Update

Recruitment ALLOB tibial fracture Phase IIb trial slower than anticipated due to pandemic

No statistically significant difference in knee pain reduction between JTA-004, placebo and active comparator, 3 months after treatment in Phase III knee osteoarthritis study

First tranche of EUR 8.0 million of the EIB financing received

Signing of research evaluation agreement with Implant Therapeutics as well as scientific advisory board appointments latest steps in creating new iMSC platform

Runway until end of Q1 2022 as development of iMSC platform accelerates

Gosselies, Belgium, 26 October 2021, 7:00 am 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 third quarter, ended 30 September 2021.

"*Bone Therapeutics is now fully focused on expanding its allogeneic differentiated MSC based cell therapy platform, beyond our current orthopedic focus for ALLOB, into other therapeutic indications,*" **said Miguel Forte, MD, PhD, Chief Executive Officer of Bone Therapeutics.** "*Our first partnership in this area now gives us access to vital iPSC technology which is an important step in the creation of our new iMSC platform. The appointment of Dr. Anne Leselbaum as our Chief Medical Officer as well as our scientific advisory board specifically for the development of Bone Therapeutic's iMSC platform will also provide crucial support to achieve this. We look forward to the development of MSC based therapies to bring options to a wider group of patients.*"

Operational highlights

- On January 12, 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. Bone Therapeutics anticipated finalizing patient recruitment in H1 2022 subject to evolution of the COVID-19 pandemic and the associated containment measures. Early recruitment rates were very promising, but the recruitment rates slowed down in recent month due to short term pandemic-related factors, such as reduced site activities due to staff availability, and number of available patients due to less accidents. The recruitment rate continues to be slower than anticipated primarily due to the pandemic impact on patient availability. Several measures (including site expansion, training, information, best practices sharing and close monitoring of progress) are being implemented in collaboration with the involved clinical research organization to improve and facilitate recruitment. The release of topline data by the end of 2022 is still currently expected. However, a delay of up to a quarter cannot be excluded.
- On August 30, 2021, Bone Therapeutics announced topline results from the Phase III knee osteoarthritis study with its enhanced viscosupplement JTA-004, its legacy non-MSC product. JTA-004 had a favorable safety profile. However, the study did not meet the primary and key secondary endpoints. No statistically significant difference in pain reduction could be observed between the treatment, placebo and comparator groups, with all treatment arms showing similar efficacy. In collaboration with existing and potential partners, Bone Therapeutics is currently evaluating the options for the future of JTA-004 development, including potential divestment or halting.
- On September 28, 2021, Bone Therapeutics signed a research evaluation agreement with Implant Therapeutics, the developer of hypoimmunogenic and safe harbor engineered IPSC derived cells. The agreement enables Bone Therapeutics to access, evaluate and materially transfer Implant Therapeutics' Induced Pluripotent Stem Cell (iPSC) derived, genetically engineered MSCs, including lines, media, differentiation protocols and expertise. The iPSCs will be used to develop Bone Therapeutics' new next generation induced pluripotent stem cell-derived mesenchymal stromal cell (iMSC) platform.

Corporate Highlights

- In July 2021, Bone Therapeutics appointed Dr. Anne Leselbaum as Chief Medical Officer. Dr. Leselbaum brings three decades of experience in strategic international clinical development, clinical operations and medical affairs. As CMO, she has taken responsibility for the leadership of all clinical development and medical affairs strategies and activities across the entire Bone Therapeutics' pipeline and oversees regulatory interactions.
- In September 2021, Bone Therapeutics appointed Lieve Creten, as interim Chief Financial Officer (CFO), succeeding Jean-Luc Vandebroek. Lieve's extensive financial experience gained as Managing Partner at Deloitte Financial Advisory Belgium will ensure the continued optimal financial control, oversight and compliance during Bone Therapeutics strategic refocus on the iMSC platform, which includes its product ALLOB.
- In October 2021, Bone Therapeutics appointed key experts to its Scientific Advisory Board (SAB). The members of the SAB consist of world-recognized scientists and clinicians in the cell and gene therapy field. The SAB has been comprised to provide additional expert guidance on the development of Bone Therapeutics' novel, next generation induced pluripotent stem cell-derived mesenchymal stromal cell (iMSC) platform.

Financial highlights

- In July 2021, Bone Therapeutics secured a loan financing of up to EUR 16.0 million with the European Investment Bank (EIB). The EIB loan financing is being disbursed in two tranches of EUR 8.0 million each, subject to conditions precedent. The payment from the EIB for the first tranche of EUR 8.0 million was received early September 2021, following the approval of the issuance of 800,000 associated warrants to the EIB at Bone Therapeutics' General Meetings at the end of August 2021.
- Bone Therapeutics also renegotiated 800 convertible bonds issued on May 7, 2020 (for an amount of EUR 2 million) to Patronale Life into a loan subject to the same repayment terms as the agreement with the EIB, with the issuance of 200,000 additional warrants unconditionally subscribed by Patronale Life under the terms and conditions decided by Bone Therapeutics' Extraordinary General Meeting.
- In July 2021, Bone Therapeutics agreed a final settlement with the Belgian Financial Services and Markets Authority (FSMA) regarding clinical studies communication issues in 2016 and 2017 for a settlement amount of EUR 500,000.
- Net cash and cash equivalents at the end of September 2021 amounted to EUR 9.3 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 EUR 16-18 million, assuming normal operation as the effect of the ongoing COVID-19 pandemic cannot be excluded. Due to the accelerated development of the iMSC platform, Bone Therapeutics anticipates having sufficient cash to carry out its business objectives till the end of Q1 2022.

Outlook for the remainder of 2021

- Bone Therapeutics will continue to expand its allogeneic differentiated MSC based cell therapy platform, beyond ALLOB, into other therapeutic indications. Bone Therapeutics is also intensifying its efforts to expand its preclinical and clinical pipeline to additional indications by enhancing and "professionalizing" the therapeutic capacity of its cell and gene therapy platform. This activity includes the development of a next generation of genetically engineered mesenchymal stromal cells (MSC) and the use of highly scalable and versatile cell sources such as induced pluripotent stem cells (iPSC).
- For the ongoing Phase IIb ALLOB clinical study in difficult tibial fractures, Bone Therapeutics' clinical team, in partnership with its clinical research organization, is continuing to institute corrective measures to mitigate the impact of the pandemic and will closely monitor the recruitment progress. Given the initial mitigation actions, Bone Therapeutics continues to expect to report topline results as scheduled by the end of 2022. However, a delay of up to a quarter cannot be excluded. Should the pandemic continue to have impact on patient availability, Bone Therapeutics may have to re-evaluate this timeline and, in that eventuality, will communicate again to the market.

- 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 ALLOB in the US.
- Bone Therapeutics will continue to hold discussions with potential partners to explore business opportunities for ALLOB while it is being evaluated in a double-blind, placebo-controlled, proof-of-concept Phase IIb study.
- As alternatives to on-going discussions including Hybrigenics, Bone Therapeutics is in the process of mandating a third party organization to explore partnership and M&A opportunities.
- LinkHealth and Pregene, Bone Therapeutics' partners in Asia continue to drive the development of ALLOB towards the submission of Investigational New Drug Application (IND) with the Chinese National Medical Products Administration (NMPA). Following a positive pre-IND meeting with the NMPA, a successful IND application would result in a new milestone payment to Bone Therapeutics.

(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 therapies at different stages ranging from pre-clinical programs in immunomodulation to mid stage clinical development for orthopedic conditions, targeting markets with large unmet medical needs and limited innovation.

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. 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.

For further information, please contact:

Bone Therapeutics SA
Miguel Forte, MD, PhD, Chief Executive Officer
Lieve Creten, Chief Financial Officer ad interim
Tel: +32 (0)71 12 10 00
investorrelations@bonetherapeutics.com

For Belgian Media and Investor Enquiries:
Bepublic
Catherine Haquenne
Tel: +32 (0)497 75 63 56
catherine@bepublic.be

International Media Enquiries:
Image Box Communications
Neil Hunter / Michelle Boxall
Tel: +44 (0)20 8943 4685
neil.hunter@ibcomms.agency / michelle@ibcomms.agency

For French Media and Investor Enquiries:
NewCap Investor Relations & Financial Communications
Pierre Laurent, Louis-Victor Delouvrier and Arthur Rouillé
Tel: +33 (0)1 44 71 94 94
bone@newcap.eu