Bone Therapeutics provides update on the progress of clinical studies

JTA-004 Phase III top-line results planned first half September

ALLOB Phase IIb currently on track but recruitment slow due to COVID-19 pandemic

Gosselies, Belgium, 19 July 2021, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, today provides an update on its two leading ongoing clinical studies.

These studies are the pivotal Phase III clinical trial with Bone Therapeutics' enhanced viscosupplement, JTA-004, targeting osteoarthritic knee pain, and the Phase IIb study with its allogeneic cell therapy product, ALLOB, in patients with difficult-to-heal tibial fractures.

The JTA-004 Phase III clinical study, having achieved target patient recruitment in December 2020, has now completed the six-month follow-up in all patients. Bone Therapeutics expects to report topline results for the 3-month primary endpoint and 6-month follow-up data in the first half of September 2021.

The Phase IIb ALLOB clinical study in high-risk tibial fractures is currently experiencing a delay in patient recruitment due to the COVID-19 pandemic and the associated containment measures. This delay is as a result of fewer accidents and reduced availability of health care facilities in the first half of 2021. Bone Therapeutics has instituted corrective measures to mitigate the impact of the pandemic on recruitment for the trial, in collaboration with its clinical research organization. At this point, Bone Therapeutics does not expect the pandemic delay in recruitment rate to have a material effect on the anticipated completion of recruitment in H1 2022. As a result, Bone Therapeutics still currently expects to deliver top line results in H2 2022 as planned. Should the pandemic continue, Bone Therapeutics may have to re-evaluate these timelines and, in that eventuality, will communicate again to the markets.

The JTA-004 Phase III study is a controlled, randomized, double-blind trial. It is evaluating the potential of a single, intra-articular injection of JTA-004 to reduce osteoarthritic pain in the knee up to 12 months, compared to placebo or Hylan G-F 20, the leading osteoarthritis treatment on the market. The study is being conducted in 22 centers across six European countries as well as Hong Kong. More than 700 patients have been treated. These patients fulfill all the strict protocol criteria including mild to moderate symptomatic knee osteoarthritis.

ALLOB is currently being evaluated in a randomized, double-blind, placebo-controlled Phase IIb study in patients with high-risk tibial fractures. This study will assess and compare against placebo, in association with standard of care stabilization surgery, the potential for ALLOB to accelerate fracture healing after 3-months follow-up and prevent late-stage complications in these patients, after a follow-up period of 6 months. ALLOB will be applied by a single percutaneous injection 24-96 hours post-definitive reduction surgery in patients with fresh tibial fractures at risk of delayed or non-union. Following the approval in seven European countries, the study is now in the process of enrolling 178 patients in over 40 sites.

About JTA-004

JTA-004 is Bone Therapeutics' next generation of intra-articular injectable for the treatment of osteoarthritic pain in the knee, a highly prevalent joint condition affecting an estimated 250 million patients worldwide. It consists of a unique mix of hyaluronic acid - a natural component of knee synovial fluid, plasma proteins, 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. In a previous randomized, double-blind Phase II study involving 164 patients, JTA-004 showed superior clinical benefit with an improved pain relief at 3 and 6 months compared to Hylan G-F 20, the global market leader in osteoarthritis treatment.

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. 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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