Bone Therapeutics publishes results of ALLOB Phase I/IIa study for the treatment of delayed-union fractures in *Stem Cell Research & Therapy*

Results showed percutaneous implantation of allogeneic bone-forming cells was well tolerated in patients and led to promising radiological and clinical improvements

Gosselies, Belgium, 30 June 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 it has published the results of its Phase I/IIa clinical trial with ALLOB, Bone Therapeutics' allogeneic bone cell therapy, in patients with delayed union fractures. The results were published in *Stem Cell Research & Therapy*, the international peer-reviewed journal focusing on translational research in stem cell therapies..

"*Approximately 5 to 10% of all long bone fractures do not heal adequately, evolving to delayed union and nonunion fractures. Currently, the only viable treatment options are to undergo painful corrective surgery with significant disease burden and long recovery times. There are estimated over 1.7 million procedures for delayed union and nonunion fractures in the EU5, US and Japan alone [(1)]. These conditions have an enormous physical and socioeconomic impact on patients, their family and the wider society,*" said **Sven Kili, MD, interim Chief Medical Officer at Bone Therapeutics**. "*These promising Phase I/IIa ALLOB results are a further demonstration of the potential for allogeneic bone cell therapy as a valuable, cost effective alternative for these patients.*"

The Phase I/IIa study was a six-month open-label trial. It evaluated the safety and efficacy of ALLOB in the treatment of delayed-union fractures of long bones. The study evaluated 21 patients. Each patient had a fracture that had failed to consolidate between three and seven months. Each patient received a single percutaneous administration of ALLOB directly into the fracture site and completed a six-month follow-up. Fracture healing of ALLOB-treated patients was assessed using both radiological evaluation (based on CT-scan) and clinical evaluation (including health status and pain).

The results published confirmed that ALLOB was generally well-tolerated and that all patients met the primary endpoint, defined as an increase of at least two points on the radiological Tomographic Union Score (TUS) or an improvement of at least 25% of patients' health status as measured by the clinical Global Disease Evaluation (GDE) score *vs.* baseline at six months post administration.

ALLOB is also currently being evaluated in a randomized, double-blind, placebo-controlled Phase IIb study in patients with high-risk fractures in the shinbone (tibia). This study will assess and compare against placebo the potential for ALLOB to accelerate fracture healing and prevent late-stage complications in these patients, in association with standard of care stabilization surgery 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. Bone Therapeutics anticipates finalizing patient recruitment in H1 2022. Topline results are expected in second half of 2022. Both events are subject to evolution of the COVID-19 pandemic and the associated containment measures resulting in fewer accidents and reduced availability of health care facilities that may result in negative impact on recruitment rates.

[1] Bone Therapeutics' estimates

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.

For further information, please contact:

Bone Therapeutics SA
Miguel Forte, MD, PhD, Chief Executive Officer
Jean-Luc Vandebroek, Chief Financial Officer
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

---

employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.

Bone Therapeutics S.A. • Rue Auguste Piccard, 37 • 6041 Gosselies • Belgium (Europe)
Phone: +32 (0) 71 12 1@0 00 • Fax: +32 (0) 71 12 10 01 • **www.bonetherapeutics.com**