Bone Therapeutics' allogeneic cell therapy product, ALLOB, shows 90% fusion rate at 24 months in Phase IIa study in lumbar spinal fusion

90% of patients show bone fusion as well as strong clinical improvements in function and pain at 24 months follow-up period with a good product safety profile

Gosselies, Belgium, 14 October 2020, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, today announces positive 24-month follow-up results for the Phase IIa study with the allogeneic cell therapy product, ALLOB, in patients undergoing lumbar spinal fusion procedures.

The 24-month data show a high percentage of successful lumbar vertebrae fusion of 90%. Patients also continue to experience important clinical improvements in function and pain, from as early as six months after treatment, up to the 24-month follow-up period.

"*Degenerative spine disorders have a major impact on the quality of life of patients. These impacts include decreases in the stability of the spine and pain in motion*," **said Dr. Alphonse Lubansu, M.D., Head of the Spinal Clinic, Erasme University Hospital, Université libre de Bruxelles**. "*The 24 month follow-up data of this Phase IIa clinical trial have demonstrated that patients treated with ALLOB in spinal fusion procedure show a high incidence in fusion, and benefit from a sustained, clinically meaningful improvement in function and pain throughout the 24 months following treatment together with a good safety profile. These results show that ALLOB in combination with the standard spine fusion surgery could be a promising treatment option to address the currently unmet needs of these patients.*"

"*This positive data for lumbar spinal fusion complements the strong Phase I/IIa results from ALLOB in patients with delayed union fractures,*" **said Miguel Forte, MD, PhD, Chief Executive Officer of Bone Therapeutics**. "*These studies provide promising clinical evidence for the potential of Bone Therapeutics' unique allogeneic cell therapy platform to address high unmet medical needs in orthopaedics and bone related disorders. We will now hold discussions with global regulators and our partners to explore a variety of options for the next stages of clinical development for ALLOB in different orthopedic indications, while pursuing the phase IIb study of ALLOB in difficult tibial fractures. In addition, the clinical results provide further evidence for the expansion of ALLOB and our platform of differentiated MSCs to other indications."*

The multi-center, open-label proof-of-concept Phase IIa study was designed to evaluate the safety and efficacy of ALLOB administered, procedure in which an interbody cage with bioceramic granules mixed with ALLOB is implanted into the spine to achieve fusion of the lumbar vertebrae. The main endpoints of the 24-month follow-up analysis included safety and radiological assessments to evaluate vertebrae fusion (continuous bone bridges) and clinical assessments to evaluate improvement in patients' functional disability as well as reduction in back and leg pain. The study evaluated 30 patients treated with ALLOB, 29 patients attended the 24-month visit.

Radiological data was collected from CT-scans at 24 months and assessed by three external readers. It showed a successful fusion of the lumbar vertebrae in 27 out of 30 patients (90%). In addition, the remaining 3 patients showed radiological evidence of bone formation. Treatment with ALLOB also resulted in a clear and statistically significant clinical improvement in function and reduction in pain over the 24-month follow-up period. Functional disability improved from the pre-treatment baseline to 24-month by a mean score of 60% ($p<0.001$) on the Oswestry Disability Index[(1)]. Back and leg pain were strongly reduced by 57 to 62% ($p<0.001$) and 68 to 70% ($p<0.001$) respectively compared to pre-treatment baseline. Treatment with ALLOB was generally well-tolerated by the patients, consistent with previous reported results.

[(1)] The Oswestry Disability Index (ODI) is an index derived from the Oswestry Low Back Pain Questionnaire used by clinicians and researchers to measure a patient's permanent functional disability. This validated questionnaire was first published by Jeremy Fairbank et al. in Physiotherapy in 1980. ODI score of 0%-20%: minimal disability; 21%-40%: moderate disability; 41%-60%: severe disability; 61%-80%: crippled; 81%-100%: bed bound.

About Spinal Fusion

Due to ageing populations and sedentary lifestyles, the number of people suffering from degenerative spine disorders continues to increase. Today, spinal fusion procedures are performed to relieve pain and improve patient daily functioning in a broad spectrum of degenerative spine disorders. Spinal fusion consists of bridging two or more vertebrae with the use of a cage and graft material, traditionally autologous bone graft or demineralised bone matrix – placed into the intervertebral space – for fusing an unstable portion of the spine and immobilizing a painful intervertebral motion segment. Over 1,000,000 spinal fusion procedures are performed annually in the US and EU, of which half at lumbar level and the market is growing at a rate of 5% per year. Although spinal fusion surgery is routine, non-fusion, slow progression to fusion and failure to eliminate pain are still frequent with up to 35% of patients not being satisfied with their surgery.

About ALLOB

ALLOB is the Company's off-the-shelf allogeneic cell therapy platform consisting of human allogeneic bone-forming cells derived from cultured bone marrow mesenchymal stem cells (MSC) from healthy adult donors, offering numerous advantages in product quality, injectable quantity, production, logistics and cost as compared to an autologous approach. To address critical factors for the development and commercialisation of cell therapy products, Bone Therapeutics has established a proprietary, optimised production process that improves consistency, scalability, cost effectiveness and ease of use of ALLOB. This optimized production process significantly increases the production yield, generating 100,000 of doses of ALLOB per bone marrow donation. Additionally, the final ALLOB product will be cryopreserved, enabling easy shipment and the capability to be stored in a frozen form at the hospital level. The process will therefore substantially reduce overall production costs, simplify supply chain logistics, improve patient accessibility and facilitate global commercialisation. The Company will implement the optimized production process for all future clinical trials with ALLOB.

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 is ready to start 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 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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