Bone Therapeutics receives Clinical Trial Application (CTA) approval for next clinical studies of its two lead candidates

Regulatory authorities approve JTA Phase III study in osteoarthritic knee pain and ALLOB Phase IIb study in difficult fractures

Gosselies, Belgium, 23 March 2020, 7am CET – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in orthopaedics and bone diseases, today announces it has received regulatory approvals for its Clinical Trial Applications for the next studies of both of its lead candidates. These two studies are the pivotal JTA-004 Phase III clinical study targeting osteoarthritic knee pain and the Phase IIb study of its allogeneic cell therapy product, ALLOB, in patients with difficult tibial fractures. The JTA-004 trial has been approved by regulatory authorities in Denmark, and the ALLOB by Belgian regulatory authorities.

Bone Therapeutics now has completed preparations for these trials. It is ready to initiate recruitment in both of these studies as soon as the current situation regarding COVID-19 allows, in those two countries. Bone Therapeutics has taken this decision to support healthcare systems in the respective trial countries, enabling them to concentrate on treating COVID-19 patients whilst necessary.

"Bone Therapeutics is now ready to commence clinical trials on both its lead products. Receiving regulatory approvals for both Clinical Trial Applications completes the preparative activity for both studies," **said Miguel Forte, CEO, Bone Therapeutics**. *"This means that as soon as the current situation allows, we will be able to start recruiting patients for both clinical studies and continue to develop options for patients suffering knee osteoarthritic pain and difficult tibial fractures, both of which are conditions with a high unmet medical need."*

The JTA-004 phase III study is a controlled, randomized, double-blind study. It will evaluate the potential of a single, intra-articular injection of JTA-004 to reduce osteoarthritic pain in the knee compared to placebo or Hylan G-F 20, the leading osteoarthritis treatment on the market. The study expects to enrol 676 patients with mild to moderate symptomatic knee osteoarthritis in approximately 20 centres in 7 European countries and Hong Kong SAR.

The ALLOB Tibial Fracture Phase IIb study is a randomized, double-blind, controlled study in which the fracture healing potential of ALLOB in patients with difficult fractures in the shinbone (tibia) will be evaluated and compared to standard of care alone after a follow-up period of 6 months. ALLOB will be applied by single percutaneous injection 24-72 hours post reduction surgery in patients with fresh tibial fractures at risk for delayed or non-union. The study is expected to enrol approximately 178 patients in approximately 40 sites in up to 7 European countries.

About JTA-004

JTA-004 is company's next generation of intra-articular injectable for the treatment of osteoarthritic pain in the knee. Consisting of a unique mix 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. In a phase II study involving 164 patients, JTA-004 showed an improved pain relief at 3 and 6 months compared to

Hylan G-F 20, the global market leader in osteoarthritis treatment.

About Knee Osteoarthritis

Osteoarthritis (OA), also known as degenerative joint disease, is the most common chronic joint condition in which the protective cartilage in the joints progressively break down resulting in joint pain, swelling, stiffness and limited range of motion. The knee is one of the joints that are mostly affected by osteoarthritis, with an estimated 250M cases worldwide.

The prevalence of knee osteoarthritis (KOA) is expected to increase in the coming years due to increasingly aging and obese population. Currently, there is no cure for KOA and treatments focus on relieving and controlling pain and symptoms, preventing disease progression, minimizing disability, and improving quality of life. Most drugs prescribed to KOA patients are topical or oral analgesics and anti-inflammatory drugs. Ultimately, severe KOA lead to highly invasive surgical interventions such as total knee replacement.

About ALLOB and Bone Therapeutics' proprietary, scalable cell therapy manufacturing process

ALLOB is the company's off-the-shelf allogeneic cell therapy platform consisting of human allogeneic bone-forming cells. These cells are derived from cultured bone marrow mesenchymal stem 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 the consistency, scalability, cost effectiveness and ease of use of the ALLOB platform. This optimized production process significantly increases the production yield, generating 100,000 of doses per bone marrow donation. Additionally, the final ALLOB product is cryopreserved, enabling easy shipment and the capability to be stored in a frozen form at the healthcare site. The process does therefore substantially improve product quality, reduce overall production costs, simplify supply chain logistics, increase patient accessibility and facilitate global commercialization compared to an autologous approach. Bone Therapeutics has implemented the optimized production process to produce clinical batches for the upcoming Phase IIb clinical trial in patients with tibial difficult-to-heal 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 bone diseases. The Company has a broad, diversified portfolio of bone cell therapies and an innovative biological product in later-stage clinical development, which target markets with large unmet medical needs and limited innovation.

Bone Therapeutics is developing an off-the-shelf protein solution, JTA-004, which is entering Phase III development for the treatment of pain in knee osteoarthritis. Positive Phase IIb efficacy results in patients with knee osteoarthritis showed a statistically significant improvement in pain relief compared to a leading viscosupplement. The clinical trial application (CTA) for the pivotal Phase III program has been approved by the Danish relevant authorities allowing the start of the study.

Bone Therapeutics' other core technology is based on its cutting-edge allogeneic cell therapy platform (ALLOB) which can be stored at the point of use in the hospital, and uses a unique, proprietary approach to bone regeneration, which turns undifferentiated stem cells from healthy donors into bone-forming cells. These cells can be administered via a minimally invasive procedure, avoiding the need for invasive surgery, and are produced via a proprietary, scalable cutting-edge manufacturing process. Following the CTA approval by the Belgian regulatory authority, the Company is ready to start the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process.

The ALLOB platform technology has multiple applications and will continue to be evaluated in other

indications including spinal fusion, osteotomy and maxillofacial and dental applications.

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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