Bone Therapeutics announces topline results from Phase III knee osteoarthritis study with its enhanced viscosupplement JTA-004

No statistically significant difference in knee pain reduction between JTA-004, placebo and active comparator, 3 months after treatment; favorable JTA-004 safety profile similar to placebo and comparator

Prime focus on the continued development and expansion of its mesenchymal stromal cell based allogeneic cell and gene therapy platform

Management to host conference call today at 4pm CEST / 10am EST - details provided below

Gosselies, Belgium, 30 August 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 that the Phase III knee osteoarthritis study with its enhanced viscosupplement JTA-004 did not meet the primary and consequently the key secondary endpoints.

The primary objective of the JTA-004 Phase III study was to demonstrate the efficacy of JTA-004 in reducing osteoarthritic knee pain compared to placebo as measured by the WOMAC® pain subscale three months after treatment. A key secondary objective was the comparison between JTA-004 and comparator Hylan G-F 20 in knee pain relief at month 3. Despite JTA-004's favorable safety profile, the study did not achieve its main objectives as no statistically significant difference in pain reduction could be observed between any of the treatment, placebo and comparator groups, with all treatment arms showing similar efficacy.

A statistically significant difference in favor of JTA-004 and the active comparator versus placebo was seen in a post-hoc analysis in a subset of patients with higher pain scores at entry.

The Company, in collaboration with existing and potential partners, will consider the options for the future of JTA-004 development.

"*The execution of the study was flawless and a good safety profile was observed in line with previous results. These JTA-004 efficacy results are disappointing. Knee osteoarthritis studies are recognized across the industry to be challenging to evaluate. They are also frequently complicated by a high placebo effect. We will continue to analyze the data and will consider potential next steps*," **said Miguel Forte, Chief Executive Officer of Bone Therapeutics**. "*We are now fully committed to the clinical development of our advanced MSC allogeneic cell and gene therapy platform. Bone Therapeutics is concentrating on the development of this platform for the large market of orthopedic indications, with ALLOB. The progress with this platform has enabled us to expand it to other indications, including immunomodulation.*"

Bone Therapeutics is focused on the development of its core assets, the allogeneic cell therapy platform, including ALLOB. ALLOB is currently being evaluated in a randomized, double-blind, placebo-controlled Phase IIb study in 178 patients with fresh tibial fractures at risk of delayed or non-union. 5% to 10% of complicated long bone fractures evolve to delayed union and non-union. This study will assess the potential for a single percutaneous injection of ALLOB to accelerate fracture healing and prevent late-stage complications in these patients. Recruitment is expected to be completed in the first half of 2022 and topline results by the end of 2022. Should the pandemic continue, Bone Therapeutics may have to re-evaluate these timelines and, in that eventuality, will communicate again to the market.

Bone Therapeutics is intensifying its efforts to expand its preclinical and clinical pipeline with additional indications by enhancing and "professionalizing" the therapeutic capacity of its cell and gene therapy platform. This 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).

Conference call

The management of Bone Therapeutics will host a conference call today at 4:00 pm CEST / 10:00 am EST. To participate in the conference call, please select your dial-in number from the list below quoting the conference ID 825 1002 3115#:

Belgium:	+32 2 290 9360
France:	+33 1 7095 0103
United Kingdom:	+44 208 080 6592
United States:	+1 646 876 9923

About JTA-004 and Phase III knee osteoarthritis study

JTA-004 is Bone Therapeutics' next generation of intra-articular injectable for the treatment of osteoarthritic pain in the knee. 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.

The JTA-004 Phase III study is a controlled, randomized, double-blind trial. It evaluates 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 is being conducted in 22 centers across six European countries as well as Hong Kong. More than 700 patients with mild to moderate symptomatic knee osteoarthritis were treated in this study.

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 250 million 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 leads to highly invasive surgical interventions such as total knee replacement.

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.

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