

Bone Therapeutics treats first patients in pivotal JTA-004 phase III knee osteoarthritis study

First patients treated following resumption of clinical activities in Hong Kong

JTA-004 phase III study approved in five of seven territories

Gosselies, Belgium, 18 May 2020, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in orthopedics and bone diseases, today announces it has commenced treating the first patients for the pivotal JTA-004 phase III clinical study in Hong Kong SAR. Several clinical trial sites in Europe are also expected to resume recruitment activities as COVID-19 lockdown measures are gradually being lifted.

The JTA-004 phase III study is a controlled, randomized, double-blind trial. 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 current osteoarthritis treatment on the market. In the study, 676 patients with mild to moderate symptomatic knee osteoarthritis are expected to be enrolled. The study will be conducted in approximately 20 centers in six European countries as well as Hong Kong SAR. Bone Therapeutics has already received approval to start the JTA-004 phase III trial in five of the seven territories. It expects to obtain approval in the remaining two countries in the course of the next month.

“The resumption of the JTA-004 phase III study with the start of patient recruitment is a very important development for patients suffering from the chronic and underserved condition of knee osteoarthritic pain and seeking novel treatments that could be provided by our enriched protein solution,” said **Miguel Forte, MD, PhD, Chief Executive Officer of Bone Therapeutics**. *“The regulatory authorities in five countries approving this trial reinforces the need for better alternatives to the existing treatments for this highly prevalent knee condition. The resumption of the phase III study would support Bone Therapeutics undertaking ongoing and future business discussions, and will also form a sound basis for our interactions with the US Food and Drug Agency.”*

“I’m very proud of all our teams for their efforts to reinitiate this crucial JTA-004 phase III study while we are still recovering from a global pandemic,” said **Olivier Godeaux, MD, Chief Medical Officer of Bone Therapeutics**. *“The support of Nordic Bioscience Clinical Development (NBCD), our clinical research partner and a specialist in osteoarthritis clinical trials, has been invaluable to quickly restarting this study in very challenging circumstances. We remain committed to developing a more effective treatment option for the many patients suffering from knee osteoarthritic pain.”*

Reporting of the topline results of the study on the 3-month primary endpoint and 6-month follow-up period is planned in the second half of 2021. Bone Therapeutics has noted that, despite lockdowns being lifted internationally, patient recruitment and the progress of the clinical trial could still be delayed with a change in the evolution of the COVID-19 pandemic. Bone Therapeutics will continue to work with all partners on taking necessary precautions for the safety of the nurses, physicians and patients involved in the studies.

JTA-004 is Bone Therapeutics’ next generation of intra-articular injectables 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 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 lead 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 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 currently in 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.

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 stromal cells from healthy donors into bone-forming cells. These cells are produced via a proprietary, scalable cutting-edge 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.

The ALLOB platform technology has multiple applications and will continue to be evaluated in other indications including spinal fusion, osteotomy, 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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