Bone Therapeutics reaches 50% treated patients in ongoing JTA-004 Phase III pivotal knee osteoarthritis study

Recruitment on track to be completed before year-end

Gosselies, Belgium, 20 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 it has already completed over 50% of its treated patients in its Phase III clinical study with the improved viscosupplement, JTA-004, in patients with knee osteoarthritis. At the current recruitment rate, and assuming no further significant disruption of health care systems worldwide due to the continuing COVID-19 pandemic, Bone Therapeutics expects to complete patient enrollment before year-end. Topline results are anticipated on the 3-month primary endpoint and 6-month follow-up period in the second half of 2021.

"*The COVID-19 pandemic has posed major challenges to patient recruitment across the industry. In spite of this, Bone Therapeutics, with the support of NBCD, has been able to treat over 50% of the patients in the JTA-004 Phase III trial in just over four months, since it started recruiting in mid-May,*" **said Miguel Forte, CEO, Bone Therapeutics**. "*This significant progress keeps us on schedule to complete recruitment before the end of the year and release topline data by second half next year. A positive outcome for this pivotal study would be a major achievement for the high unmet medical need of the estimated 250 million patients worldwide suffering from knee osteoarthritis, a very painful and debilitating condition."*

The JTA-004 Phase III study is a controlled, randomized, double-blind trial. It is evaluating 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. The study is being conducted in six European countries as well as Hong Kong SAR. Since the initiation of the recruitment in mid-May 2020, 50% of the targeted assessable patients have already been treated. The study plans to enroll 676 patients fulfilling the protocol criteria with mild to moderate symptomatic knee osteoarthritis.

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 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. In a previous randomized, double-blind Phase II study involving 164 patients, JTA-004 showed superior clinical benefit with an improved pain relief at 3 and 6 months compared to Hylan G-F 20, the global market leader in osteoarthritis treatment.

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.

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.

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' 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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