

## Bone Therapeutics advances JTA-004 into pivotal Phase III study

**Clinical trial application for pivotal JTA-004 Phase III study submitted**

**Start patient enrollment anticipated early 2020 with topline results expected in Q2 2021**

**Gosselies, Belgium, 20 December 2019, 7am CET – BONE THERAPEUTICS** (Euronext Brussels and Paris: BOTHE), the leading biotech company focused on the development of innovative cell and biological therapies to address high unmet medical needs in orthopaedics and bone diseases, today announces that the Clinical Trial Application is being submitted to the competent authorities to initiate the pivotal Phase III study with the enhanced protein solution, JTA-004, in patients with knee osteoarthritis. The start of patient enrollment is anticipated early 2020.

The JTA-004 Phase III study is a placebo and active-controlled, randomized, double-blind study to 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 is expected to enrol 676 patients with mild to moderate symptomatic knee osteoarthritis in 20 centres in 5 European countries and Hong Kong SAR. The Company has contracted Nordic Bioscience, a contract research organisation specialized in osteoarthritis clinical trials, to oversee the study. The first results of the study are anticipated in the second quarter of 2021 after a follow-up period of 3 months.

**Jean Stéphane, Chairman of Bone Therapeutics commented:** *“Following the promising safety and efficacy results from the previous study with JTA-004, we are pleased that the Clinical Trial Application for the Phase III study is now being submitted. Based on its unique composition, JTA-004 could offer an improved treatment option to the numerous patients suffering from knee osteoarthritis. The CTA filing is an important milestone in the development of this core pipeline asset and we look forward to starting enrolling patients in this study in the first months of 2020.”*

## ● **About Bone Therapeutics**

*Bone Therapeutics is a leading biotech company focused on the development of innovative products to address high unmet needs in orthopaedics and bone diseases. Based in Gosselies, Belgium, the Company has a broad, diversified portfolio of bone cell therapy and an innovative biological product in later-stage clinical development across a number of disease areas, 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 expected to enter Phase III development for the treatment of pain in knee osteoarthritis further to reported positive Phase IIb efficacy results in patients with knee osteoarthritis, showing a statistically significant improvement in pain relief compared to a leading viscosupplement. The Phase III program with JTA-004 in patients with knee osteoarthritis shall start in Q1 2020 and the Company is currently submitting the related clinical trial application (CTA) with the regulatory authorities in Europe.*

*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, cutting-edge manufacturing process. Further to recently reported strong Phase IIa efficacy and safety results for ALLOB, the Company plans to submit a CTA with the regulatory authorities before year-end to initiate a Phase IIb clinical trial with ALLOB in patients with difficult-to-heal fractures, using its optimized production process.*

*The Company's lead product candidate in the ALLOB product pipeline is a regenerative cell therapy that is expected to enter Phase IIb clinical development for the treatment of difficult-to-heal fractures. The ALLOB platform technology has many other applications and will continue to be evaluated in other applications like spinal fusion, maxillofacial, dental and osteotomy.*

*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. Further information is available at [www.bonetherapeutics.com](http://www.bonetherapeutics.com).*

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