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.