

Bone Therapeutics expands its delayed-union program with ALLOB® into multiple fractures

- *Extension of ongoing Phase I/IIA delayed-union trial to multifocal delayed-union fractures*
- *Evaluation of safety and efficacy of higher doses of ALLOB®*

Gosselies, Belgium, 18 January 2016 - BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in the field of bone fracture repair and bone fracture prevention, today announces the initiation of a Phase IIA study for the treatment of multiple delayed-union fractures with ALLOB®, its novel allogeneic bone cell therapy product. The Competent Authorities in Belgium and Germany have approved the study, which will complement the ongoing Phase I/IIA delayed-union study.

The new Phase IIA study aims to extend the ongoing trial from the treatment of single fractures to multiple fractures. The study will enrol 12 patients, diagnosed with multiple delayed-union fractures of long bones, across six sites in Belgium and four sites in Germany. Patients will receive two to four percutaneous injections of ALLOB® at two, three or four fracture sites on the same or different long bones, while a single dose at one site is used in the initial delayed-union study. The study will thus allow the evaluation of the safety and efficacy of higher doses of ALLOB®.

Patients will be recruited in cohorts of four and initial safety data of each cohort will be analysed by the Safety Monitoring Committee before recruitment of the next patients to ensure maximum patient safety. Fracture healing in the ALLOB®-treated patients will be evaluated over a six-month period using clinical and radiological parameters.

Enrico Bastianelli, CEO of Bone Therapeutics, commented: *"We are pleased to continue the progress in our clinical strategy, intended to increase the potential market for ALLOB®. This new study is the next step in the development of our delayed-union program and it will allow us to provide patients who might be facing a long road of complicated surgeries and rehabilitation with a minimally invasive alternative."*

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About ALLOB®

ALLOB® is a first-in-class allogeneic differentiated osteoblastic (bone-forming) cell therapy product developed for the treatment of orthopaedic conditions and bone diseases. Allogeneic cell therapy involves the harvesting of cells from a healthy donor, rather than from the treated patient. ALLOB® is currently being evaluated in three Phase I/IIA clinical trials for delayed-union fractures, spinal fusion and the revision of failed spinal fusions. ALLOB® has been classified as a tissue engineered product under the ATMP regulation 1394/2007/EMA and received orphan drug designation from the EMA (Europe) and FDA (US) for two indications, osteonecrosis and osteogenesis imperfecta.

About Delayed-Union Fractures

A delayed-union fracture is defined as a fracture that has not healed within the expected normal period after the initial injury (i.e. 3 to 4 months) and is at risk of non-healing. Traditional options for the treatment of an impaired fracture (i.e. bone graft) typically involve highly invasive surgery, which can be painful and require months of rehabilitation with the risk of serious complications. Due to the risks of current treatments, orthopaedic surgeons often take a 'wait-and-see' approach, sometimes for several months, which delays the patient's return to a normal life and leads to a significant burden on society. ALLOB® has the potential to become a first-line and early treatment for delayed-union fractures, thanks to its minimally invasive administration that avoids the need for major surgery. Bone Therapeutics has already demonstrated efficacy in the first four-patient cohort of its ALLOB® Phase I/IIA trial for delayed-union fractures and completed treatment without any safety concerns in the second cohort.

About Bone Therapeutics

Bone Therapeutics is a leading biotechnology company specializing in the development of cell therapy products intended for bone fracture repair and fracture prevention. The current standard-of-care in this field involves major surgeries and long recovery periods. To overcome these problems, Bone Therapeutics is developing a range of innovative regenerative products containing osteoblastic/bone-forming cells, administrable via a minimally invasive percutaneous technique; a unique proposition in the market.

PREOB®, Bone Therapeutics' autologous bone cell product, is currently in pivotal Phase IIB/III clinical studies for two indications: osteonecrosis and non-union fractures, and in Phase II for severe osteoporosis. ALLOB®, its allogeneic "off-the-shelf" bone cell product, is in Phase I/IIA for the treatment of delayed-union fractures and lumbar fusion for degenerative disease of the spine. The Company also runs preclinical research programs and develops novel product candidates.

Founded in 2006, Bone Therapeutics is headquartered in Gosselies (South of Brussels, Belgium). Bone Therapeutics' regenerative products are manufactured to the highest GMP standards and are protected by a rich IP estate covering 11 patent families. Further information is available at www.bonetherapeutics.com.

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