

Bone Therapeutics presents ALLOB[®] pre-clinical and early clinical efficacy data in spinal fusion at the ‘Clinical Applications of Stem Cells’ Conference

Successful spinal fusion achieved in first patient within 12 months

Gosselies, Belgium, 24 February 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 that it has presented pre-clinical and positive early clinical efficacy data of its ALLOB[®] Phase IIA spinal fusion trial. These preliminary data, presented at the [Clinical Applications of Stem Cells Conference](#), 24-25 February 2016 in Singapore, show spinal fusion on CT scans and absence of intervertebral motion on dynamic x-rays.

Spinal fusion is the current standard of care for degenerative disc disease to relieve pain and improve function. However, progression to fusion with current treatments is slow, usually taking 18 to 24 months. Furthermore, the surgery may result in lack of fusion and continuing pain, leaving up to 25% to 30% of patients unsatisfied with their surgery.

Bone Therapeutics is investigating a unique approach where the interbody cage is implanted according to the standard-of-care surgical approach and supplemented with ALLOB[®] in combination with bioceramic granules. Preclinical results demonstrated that the combination of bioceramics with ALLOB[®] cells significantly increased new bone formation and fusion in comparison with bioceramics alone.

Safety and efficacy of the implantation of ALLOB[®] cells mixed with bioceramic granules in lumbar spinal fusion is evaluated in the ongoing pilot Phase IIA study with ALLOB[®] using clinical and radiological parameters. In this proof-of-concept study, the first out of 12 patients treated has now completed the 12-month follow-up period. The presence of bone bridges between the vertebrae was demonstrated on CT scans as early as 6 months after treatment and dynamic x-rays revealed the absence of motion of the vertebral bodies, indicating a successful fusion. In addition, this patient experienced pain relief six months after the treatment, as assessed by the Visual Analogue Scale (questionnaire).

Enrico Bastianelli, Chief Executive Officer of Bone Therapeutics, commented: *“These preliminary efficacy data, alongside the confirmed safety profile in the first 12 patients, strengthen our confidence in the clinical potential of ALLOB[®] for spinal fusion procedures, where there is a high rate of failure in the existing standard of care. We are pleased to have been able to present these data at the Clinical Applications of Stem Cells conference, and look forward to reporting further efficacy data.”*

The poster covering the content of the presentation is available on the website of Bone Therapeutics, in the section [Investors/Presentations](#).

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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 spinal fusion

Spinal fusion is considered the gold standard surgery for treating a broad spectrum of degenerative spine disorders, including degenerative disc disease to relieve pain and improve function. Spinal fusion consists of bridging two or more vertebrae with the use of a cage and graft material, traditionally autologous bone graft, for fusing an unstable portion of the spine or immobilizing a painful vertebral motion segment. Despite the fact that spinal fusion surgery is routine, non-union and failure to relieve lower back pain are unfortunately still frequent as up to 25 to 30% of spinal fusion patients are not completely satisfied with their surgery. Bone Therapeutics' products are intended to decrease the failure rate of spinal fusion surgeries.

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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