Bone Therapeutics completes recruitment of its ALLOB® Phase IIA spinal fusion study

Trial extended to assess early onset and dynamics of fusion process

Gosselies, Belgium, 3 May 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 prevention and spinal fusion, today announces that it has completed recruitment of its Phase IIA spinal fusion study for its allogeneic cell therapy product ALLOB® ahead of schedule. The Company also announced that it is further extending the trial to assess early onset of bone formation and fusion. The trial extension has been submitted and approved by the Ethics Committee and Competent Authorities.

In spine fusion, Bone Therapeutics is investigating a unique approach where an interbody cage is implanted in-between the damaged vertebrae 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 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 this Phase IIA study using clinical and radiological parameters at 6 and 12 months after treatment. In total, of the 18 patients enrolled in the study, 16 were eligible and 15 have been treated*. No treatment-related safety concerns were reported. It is expected that efficacy data from the first four patients from the study will be reported by the end of the second quarter of 2016 with the complete set of efficacy results expected in the second quarter of 2017.

In addition to high clinical demand, the extension has been designed to study the detailed dynamics of the fusion. In the extension trial, 16 patients will be treated and evaluated earlier with review of the patient's progress after 3, 6 and 12 months.

Enrico Bastianelli, Chief Executive Officer of Bone Therapeutics, commented: "*We are very happy with the rate at which this trial has progressed. With the spinal fusion program we intend to improve the current surgical procedure and increase its chance of success. The large unmet need of this indication, alongside evidence of fusion earlier than anticipated, have led us to extend the trial. We look forward to communicating on the next efficacy results of this promising trial.*"

*One out of the 16 eligible patients was not treated as the surgeon decided to change the surgical procedure.

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 1394/2007EMA 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 II for the treatment of delayed-union fractures and lumbar fusion for degenerative disease of the spine, including a minimally invasive therapy for failed spinal fusions. 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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