

Press Release

17 February 2016

## **Bone Therapeutics treats 12 patients without safety concerns in ALLOB® Phase IIA spinal fusion trial**

*Recruitment almost complete with four patients left to treat*

**Gosselies, Belgium, 17 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 it has now treated 12 patients in its ALLOB® Phase IIA spinal fusion trial without any safety concerns. The trial is progressing quickly with only one more patient cohort of four patients to treat.

Spinal fusion is the current standard of care for degenerative disc disease to relieve pain and improve function. However, this surgery often results in lack of fusion and continuing pain, leaving 25% to 30% of patients unsatisfied with their surgery. Bone Therapeutics is seeking to address this through the inclusion of its allogeneic bone forming cell product ALLOB® in the procedure.

The pilot Phase IIA study with ALLOB® will enrol a total of 16 patients with symptomatic degenerative lumbar disc disease who require interbody fusion surgery. An interbody cage is implanted according to the standard-of-care surgical approach, supplemented with ALLOB® in combination with bioceramic granules. Safety and efficacy of this treatment is assessed over 12 months, using clinical and radiological evaluations. The trial is currently running in eight centres across Belgium. Today, the procedure has been performed in 12 patients without any complications or safety issues.

On February 24, the Company will present efficacy data on the first patient treated in the trial at the 'Clinical Applications of Stem Cells' Conference in Singapore. The presentation is entitled *Clinical Application of Osteoblastic Cell-based Therapy in Spinal Fusion* and will be presented by Wendy Sonnet, PhD, clinical project manager at Bone Therapeutics.

**Enrico Bastianelli, Chief Executive Officer of Bone Therapeutics, commented:** *"We are pleased to see consistent safety being reported with our allogeneic bone cell therapy product. Recruitment for the spinal fusion trial is progressing quickly and is now 75% complete. We look forward to updating the market on the first efficacy results."*

**-Ends-**

### **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](http://www.bonetherapeutics.com).



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