Press release 15 December 2015

Bone Therapeutics completes recruitment of the first half of patients in ALLOB® Phase IIA spinal fusion trial

ALLOB®'s positive safety profile confirmed at mid-point in trial

Gosselies, Belgium, 15 December 2015 - 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 successfully completed recruitment of the second cohort of four patients in its ALLOB® Phase IIA spinal fusion trial without any safety concerns. Recruitment for this trial remains on track at the midpoint of the trial, with eight out of a total of 16 patients treated.

Spinal fusion is considered the gold standard for the treatment of a broad spectrum of spine disorders and aims to relieve pain and improve function. Approximately one million spinal fusion surgeries are performed each year in Europe and the US (of which approximately half involve lumbar spinal fusion)[1] and the global market is estimated to reach $7 billion by 2017.[2] Although spinal fusion surgery is routine, it is associated with failure rates of up to 35%.[3] Bone Therapeutics' cell therapy product ALLOB® has been designed to accelerate the fusion process and reduce the failure rate of current surgeries.

The pilot Phase IIA study will enrol 16 patients with symptomatic degenerative lumbar disc disease who require interbody fusion surgery.[4] An interbody cage is implanted according to the standard-of-care surgical approach, which will be supplemented with ALLOB® in combination with bioceramic granules. Safety and efficacy of this treatment will be assessed over 12 months, using clinical and radiological evaluation. The trial is currently running in eight centres across Belgium. Today, the procedure has been performed in eight patients without any complications or safety issues.

ALLOB® is also being evaluated in the treatment of delayed-union fractures and has already reported strong safety and efficacy results. Recently, the Company initiated a novel Phase IIA study with ALLOB® for the treatment of patients with failed spinal fusions. This is the first minimally invasive revision spinal surgery using a bone cell therapy product.

Enrico Bastianelli, CEO of Bone Therapeutics, commented: *"We are pleased to report today that the spinal fusion trial is on schedule with half of the patients now treated without any safety concerns. We expect to update the market in the first half of 2016 on the efficacy of ALLOB® in the first cohort patients in this trial after the 12-month follow-up period. The excellent safety and efficacy results reported for ALLOB® so far reinforce our confidence in the success of the product and we look forward to further positive data in 2016."*

Footnotes

[1] Company estimates based on: Hospital discharge data from the Agency for Healthcare Research and Quality for the US; Statistics by the Bundesamt Wiesbaden (Germany); Medtech European Markets for Spinal Fusion Products, March 2006.

[2] Global Data report (2014): Spinal fusion – Global Analysis and Market Forecasts.

[3] Aghion et al. (2012) Failed back syndrome. Medicine & Health / Rhode Island 95:391-393.

[4] Interbody fusion is a type of spinal fusion surgery that involves removal of the disc between two vertebral bodies. To maintain the normal alignment of the spine, an implant, such as a spacer or cage, will be inserted in the space created by the removal of the disc. Subsequently, a bone graft or bone graft substitute is placed between the neighbouring vertebrae to stimulate the fusion process.

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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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