Press Release September 2014

Bone Therapeutics receives clearance for ALLOB® phase II trial in spinal fusion

Bone Therapeutics' allogeneic osteoblastic cell therapy product enters the clinic to facilitate spinal fusion in patients with degenerative lumbar disc disease

Gosselies, Belgium, 15 September 2014 - BONE THERAPEUTICS, the regenerative therapy company addressing unmet medical needs in the fields of bone diseases and orthopaedics, announces today that it has received clearance from the Competent Authorities and Central Ethics Committee in Belgium for a phase II proof-of-concept study to assess safety and efficacy of its allogeneic[1] osteoblastic cell therapy product ALLOB® in spinal fusion procedures for degenerative lumbar disc disease.

Bone Therapeutics aims to investigate ALLOB®'s potential to fulfil this unmet medical need and improve spinal fusion surgery outcomes. ALLOB® has already shown the required osteoinductive, osteogenic and osteoconductive features[2] for bone formation enhancement as well as excellent safety and efficacy in preclinical studies and is currently being evaluated in a phase I/IIa trial for delayed-union fractures.

In this pilot proof-of-concept study, 16 patients with symptomatic degenerative lumbar disc disease that require interbody fusion will be treated with a single dose of ALLOB® mixed with bioceramic granules to promote bone formation and fusion at the degenerative disc level. The use of a bioceramic scaffold mixed with ALLOB® cells is intended to promote bone formation by (i) providing biologically active osteoblastic cells, (ii) restoring a healthy bone environment, and (iii) guiding growth in 3-dimensions. Patients will be enrolled in 4 centres and safety and efficacy of the treatment will be monitored over 12 months by clinical (Oswestry Disability Index) and radiological (fusion progression) evaluation, with an additional 24-month post-study follow-up.

Back pain is a widespread medical disorder in industrialized societies and several pathologies require spinal surgery. Around 1.3 million spinal fusions are performed each year in Europe and the USA, the majority of which are to address degenerative lumbar disc disease. Despite the frequency of this surgery, non-union of bone and persistent pain following the intervention is still extremely common. Further improvements would thus be extremely beneficial to improve safety and efficacy.

Enrico Bastianelli, CEO of Bone Therapeutics commented, "This new clinical trial clearance from the Competent Authorities in Belgium is an important milestone in the

[1] Where cells are derived from a healthy, universal donor, rather than the patient.
[2] Induction of bone formation (osteoinduction), new bone support (osteoconduction) and production of mature bone (osteogenic) are the 3 essential features to healthy bone formation

development of ALLOB® and further validates Bone Therapeutics' clinical, regulatory and manufacturing capabilities."

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About ALLOB®

ALLOB® is a first-in-class allogeneic osteoblastic cell product with regenerative properties, developed for the treatment of bone diseases. "Allogeneic" means that the cells are harvested from a healthy, universal donor, as opposed to "autologous" where the cells come from the patient him/herself. ALLOB® is currently tested in two Phase I/IIa clinical trials for the treatment of delayed union fractures and lumbar fusion for degenerative disease of the spine. ALLOB® also has the potential to be administered systemically to treat orthopaedic conditions such as osteogenesis imperfecta, a rare genetic bone disease characterized by bone fragility and fractures. ALLOB® has been classified as a tissue engineered product under the ATMP regulation 1394/2007EMA.

About Bone Therapeutics

Bone Therapeutics is a leading biotechnology company specializing in the development of innovative regenerative therapies for the treatment of orthopaedic conditions. 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 products containing regenerative osteoblastic/bone forming cells, administrable via a minimally invasive percutaneous technique; a unique proposition in the market.

PREOB®, Bone Therapeutics' autologous cell product, is currently in pivotal Phase III clinical studies for two indications: osteonecrosis and non-union fractures, and in Phase II for treatment resistant osteoporosis. ALLOB®, its allogeneic cell product, is in Phase II 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 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 10 patent families. Further information is available at www.bonetherapeutics.com

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