

ALLOB® Delayed-Union Program Awarded at Cells Orthopedics Conference

Peer review panel praises scientific value and medical relevance of ALLOB® Phase I/IIA in delayed-union fractures

Gosselies, Belgium, 11 December 2015 - BONE THERAPEUTICS, the bone cell therapy company addressing high unmet medical needs in the field of bone fracture repair and bone fracture prevention, announces that it has been awarded a gold prize for an abstract on the Phase I/IIA trial of its ALLOB® allogeneic cell therapy in delayed-union fractures of long bones.

The abstract, “A pilot Phase I/IIA, multicentre, open proof-of-concept study on the efficacy and safety of allogeneic osteoblastic cells (ALLOB®) implantation in non-infected delayed-union fractures” by Elisa Llinares, PhD, Audrey Colliou, PharmD and Enrico Bastianelli, MD, MBA, was awarded the top prize on December 4th, following the Cells: Orthopedics conference 2015 in Palma Mallorca, Spain, held November 13th – 15th. The abstract beats other contestants to be recognised by the Clinical and Scientific Advisory Board of the conference based on scientific or clinical value, originality, categorical relevance and overall presentation and conclusion. The poster can be accessed here: <http://rgnmed.com/gold-winner-osteoblastic-cell-based-therapy-for-delayed-union-fractures/>.

The poster outlines the Company’s unique approach to the development of cell therapy products for bone fracture repair and prevention, details findings from preclinical studies on Bone Therapeutics’ bone formation model and outlines the parameters of the ongoing Phase I/IIA study of ALLOB® in delayed-union fractures.

This Phase I/IIA trial is a six-month, open-label trial for the treatment of delayed-union fractures of long bones. The Company recently reported excellent safety and efficacy from the treatment of the initial four patients and has successfully treated a second cohort of patients without any safety issues. The trial is targeting the recruitment of 32 patients in Belgium, Germany and the UK but is flexible and could be stopped earlier if efficacy is seen following an interim data analysis of the first 16 patients. The poster presented outlined preclinical findings before updating on the progress of the Phase I/IIA trial.

Enrico Bastianelli, CEO of Bone Therapeutics, commented: *“This is the first trial to investigate an allogeneic bone cell therapy product, and we are very enthusiastic about the initial efficacy and safety data. The standard of care for the treatment of an impaired fracture, such as bone graft, typically involves highly invasive surgery which can be painful and requires months of rehabilitation with the risk of serious complications. Due to the risks of the current treatment, orthopaedic surgeons often take a ‘wait and see’ approach to the treatment of delayed-union fractures, sometimes for months, which delays the patient’s return to a normal life and leads to a significant burden on society. We are therefore thrilled that the judges at the Cells: Orthopedics conference 2015 have recognised the significance of the work we are doing in orthopaedics and with our allogeneic regenerative medicine approach.”*

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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® 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 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. 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 9 patent families. Further information is available at www.bonetherapeutics.com.

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