Press Release October 2014

Bone Therapeutics extends ALLOB® phase I/IIa trial to Germany

Four German centres now approved to assess novel allogeneic regenerative therapy for the treatment of delayed union fractures

Gosselies, Belgium, 9 October 2014 - BONE THERAPEUTICS, the regenerative therapy company addressing unmet medical needs in the fields of bone diseases and orthopaedics, announces today that its phase I/IIa trial with the allogeneic[1] osteoblastic cell therapy product ALLOB® for the treatment of delayed union fractures has been approved by the Paul-Ehrlich-Institute, the national authority in Germany.

Four major German centres: Universitätsklinikum Köln, Universität Würzburg Orthopädische Klinik, Universitätsklinikum Schleswig Holstein in Lübeck and Klinikum rechts der Isar in München, are now approved to conduct the proof of concept phase I/IIa trial of ALLOB®, the first ever clinical trial approved for allogeneic differentiated osteoblastic cell therapy product developed for the treatment of orthopaedic conditions. ALLOB® has already shown bone-forming properties as well as demonstrated safety and efficacy in preclinical studies. A total of nine centres across Belgium and Germany are now approved.

This will only be the second clinical trial approval of an allogeneic regenerative therapy product authorized in Germany in an orthopaedic condition. The approval demonstrates the robustness of Bone Therapeutics' application as Germany's competent authorities are known to have some of the strictest guidelines for the development of Advanced-Therapy medicinal Products (ATmP) which ALLOB® is classified as.

The ongoing phase I/IIa study is a six month open-label trial to evaluate the safety and efficacy of ALLOB® in the treatment of delayed union fractures of long bones. In total, 32 patients will be enrolled in about 15 centres (a further 16 additional patients may be enrolled upon the results of the interim analysis). They will receive a single percutaneous administration of ALLOB® directly into the fracture site. ALLOB®-treated patients will be assessed in comparison to baseline at two weeks, one, three and six months using clinical (e.g., pain, weight-bearing) and radiological evaluation.

Traditional options for the treatment of an impaired fracture (i.e., bone graft) typically involve highly invasive surgery, which can be painful and require months of rehabilitation with the risk of serious complications (such as deep bone infection). Due to the risks of the current treatment, orthopaedic surgeons often take a "watch and wait" approach to the treatment of delayed union fractures, sometimes for several months, which delays the patient's return to a normal life and leads to a significant financial burden to society. ALLOB® has the potential to become a first-line and early treatment for delayed union fractures, thanks to its minimally invasive administration which avoids the need for surgery.

Enrico Bastianelli, CEO of Bone Therapeutics commented: "The extension of the phase I/IIb study into Germany demonstrates the strong momentum in the clinical development of ALLOB®, our unique "off-the-shelf" regenerative therapy product. ALLOB®'s minimally invasive administration and low side effect profile would not only have a significant impact as a first line treatment of delayed union fractures but could also offer potential to treat multiple orthopaedic indications."

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[1] Where cells are derived from a healthy, universal donor, rather than the patient.

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 Delayed Union Fractures

A delayed union fracture is defined as a bone that has not healed within the expected normal period of time after the initial injury (i.e., 3 to 4 months) and is at risk of non-healing.

About Bone Therapeutics

Bone Therapeutics is a leading biotechnology company specializing in the development of innovative regenerative therapies for the treatment of bone diseases and orthopaedic conditions. The current standard of care in this field often involves major surgery 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 unique 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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