Press Release 25 June 2014

Bone Therapeutics Starts Patient Treatment in First Ever Clinical Trial with Allogeneic Bone Cell Therapy Product

Minimally invasive bone forming product ALLOB® in Phase I/IIa trial for delayed union fracture

Gosselies, Belgium, 25 June 2014 - BONE THERAPEUTICS, the regenerative therapy company addressing unmet medical needs in the field of bone diseases and orthopaedics, today announces that the first patient has been treated with its novel allogeneic osteoblastic (bone-forming) cell therapy product ALLOB® in its phase I/IIa study for the treatment of delayed union fractures.

ALLOB® is the first ever allogeneic differentiated[1] osteoblastic cell therapy product developed for the treatment of orthopaedic conditions. Allogeneic cell therapy involves the harvesting of cells from a healthy, universal donor, rather than from the patient being treated. ALLOB® has shown safety and efficacy in preclinical studies and does not require any immunosuppressive side therapy.

ALLOB® has the potential to become a first-line treatment for impaired fracture healing, thanks to its minimally invasive percutaneous administration. Delayed union fractures, defined by the absence of fracture healing after 3 months, affect around 600,000 to 900,000 new patients a year in Europe and the US. The current standard of care for delayed union fractures involves highly invasive surgery, which takes up to several hours followed by a long hospitalization. By contrast, this first administration of ALLOB® required about 20 minutes and took place at the day-clinic. ALLOB® is injected by the orthopaedic surgeon in a single dose percutaneously, directly into the fracture site. No side-effects have yet been reported.

This first-in-human, proof-of-concept, 6 months open-label phase I/IIa study is evaluating the safety and efficacy of ALLOB® in the treatment of delayed union fractures of long bones. ALLOB®-treated patients will be assessed in comparison to baseline at 2 weeks, 1, 3 and 6 months using clinical (e.g., pain, weight-bearing) and radiological evaluation. Ultimately, 32 patients with delayed union fractures will be enrolled in the study.

Enrico Bastianelli, Chief Executive Officer of Bone Therapeutics commented: "Treating a patient for the first time with our allogeneic product ALLOB® is a significant step forward for the progression of Bone Therapeutics' regenerative therapy pipeline. Our allogeneic approach will lead to an "off-the-shelf" approach to treatment whilst offering delayed union patients the potential for a significant improvement in their condition without the need for invasive surgery. ALLOB® has the potential to add significant shareholder value as it could address multiple orthopaedic conditions as a first line treatment. This first in human trial is an important milestone both for realizing benefits for the patients as well as creating value for the Company."

1. Differentiated osteoblastic cells showing higher efficacy compared to undifferentiated stem cells – Undale – JOR December 2011
2. Recent literature (Ruetze and Richter, 2014) indicates that bone marrow derived cells perform considerably better than adipose derived mesenchymal stem cells

About ALLOB®

ALLOB® is Bone Therapeutics' allogeneic bone cell therapy product. "Allogeneic" means that the cells are harvested[2] from a healthy, universal donor, rather than from the patient him/herself (autologous). Currently in a Phase I/IIa clinical trial for delayed union fractures, ALLOB® also has the potential to be applied for treating other orthopaedic conditions as well as for systemic applications such as in 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. Around 600,000 to 900,000 patients are affected by delayed union each year. Traditional options for the treatment of impaired fracture healing typically involve highly invasive surgery, which can be painful and require months of rehabilitation with no guarantee of success.

About Bone Therapeutics

Bone Therapeutics is a regenerative therapy company specializing in addressing unmet medical needs in the field of orthopaedics via a minimally invasive approach. Utilizing the Company's unique knowledge of the bone/joint physiology and long-standing expertise in cell therapy and cell transplantation, Bone Therapeutics has created a fully integrated business with an advanced product pipeline comprising novel bone cell products, tailored in-house production methods and minimally invasive treatment techniques.

Bone Therapeutics autologous bone cell product, PREOB®, is currently in phase III clinical trials for the treatment of osteonecrosis and non-union fractures. Bone Therapeutics is also developing an allogeneic bone cell therapy product, ALLOB®, which entered the clinic in 2014 for the treatment of delayed union fractures. All of Bone Therapeutics' cell therapy products are manufactured to the highest GMP standards, comply with all regulations and are protected by a rich IP estate.

The bone disease and reconstruction market is one of the largest healthcare markets in the world, with more than 4 million procedures requiring bone grafts performed annually in Europe and the USA alone. Bone Therapeutics is operating in areas where demand for new products is high and competition is low. Founded in 2006, Bone Therapeutics is privately held and headquartered in Gosselies (south of Brussels), Belgium. Further information is available at: bonetherapeutics.com

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