Press Release October 2013

Bone Therapeutics receives clearance for ALLOB® phase I/IIa trial

Bone Therapeutics' allogeneic osteoblastic product to enter clinic for the treatment of delayed union fractures

Gosselies, Belgium, 1st October 2013 - BONE THERAPEUTICS, the leading biopharmaceutical company focused on innovative cell therapy products for the treatment of bone diseases, announces today that it has received clearance from the Competent Authorities in Belgium and the UK for a phase I/IIa trial with its allogeneic cell therapy product ALLOB® for the treatment of delayed union fractures.

ALLOB® is an allogeneic[1], osteoblastic (i.e. bone-forming) cell therapy product. ALLOB® has already shown safety and efficacy in preclinical studies and has the potential to become a first-line treatment for impaired fracture healing, thanks to its minimally invasive percutaneous administration, avoiding the need for surgery.

This first-in-human, proof-of-concept, phase I/IIa study is a 6 months open-label trial to evaluate the safety and efficacy of ALLOB® in the treatment of delayed union fractures of long bones. Thirty-two patients will be enrolled in 10 centers. 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 2 weeks, 1, 3 and 6 months using clinical (e.g., pain, weight-bearing) and radiological evaluation.

Bone Therapeutics has already secured both 'Tissue Establishment' and 'GMP' Accreditation for the in-house manufacturing of ALLOB®. This not only allows Bone Therapeutics to have enhanced control over ALLOB®'s production, but secures the manufacturing runway for scale up of production to support ALLOB®'s further development.

Enrico Bastianelli, CEO of Bone Therapeutics commented, "This new clinical trial clearance from the Competent Authorities in Belgium and the UK is an important milestone in the development of ALLOB® and further validates Bone Therapeutics' clinical, regulatory and manufacturing capabilities. The only way to address delayed union fractures currently is invasive surgery which could have severe complications and a long hospital stay. With ALLOB®'s bone regenerative mode of action and minimally invasive administration, Bone Therapeutics' allogeneic product could become a first-line treatment."

About ALLOB®

ALLOB® is Bone Therapeutics' allogeneic bone cell therapy product. "Allogeneic" means that the cells are harvested from a healthy, universal donor, rather than from the patient (autologous). Currently in a Phase I/IIa clinical trial for delayed union fractures, ALLOB® also has the potential 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 one million 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 leading international biopharmaceutical company focused on innovative cell therapy products for the treatment of bone diseases, an area of significant unmet medical need. Utilizing the Company's unique knowledge of the bone 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' lead product, PREOB®, is an autologous bone cell product, currently in Phase III clinical trials for the treatment of osteonecrosis and non-union fractures as well as in a Phase II trial for severe osteoporosis. Bone Therapeutics is also developing an allogeneic bone cell therapy product, ALLOB®, which is in a Phase I/IIa clinical trial for delayed union fractures. All of Bone Therapeutics' cell therapy products are manufactured to the highest GMP standards and 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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1 : Where cells are derived from a healthy, universal donor, rather than the patient.