

## Bone Therapeutics treats first patients in PREOB® pivotal phase IIb/III trial for the treatment of non-union fractures

**Gosselies, Belgium, 26<sup>th</sup> November 2013 - BONE THERAPEUTICS**, the regenerative therapy company addressing unmet needs in the field of orthopaedics via a minimally invasive approach, today announces it has received clearance from the Competent Authorities in Belgium, France and the Netherlands to initiate a phase IIb/III trial with its autologous cell therapy product, PREOB®, for the treatment of non-union fractures. First patients have already been treated in Belgium.

PREOB® is a first-in-class autologous osteoblastic/bone forming cell product. It is positioned as a first-line treatment for non-union fractures as it is administered via a minimally invasive approach directly into the fracture site, thereby avoiding the need for open surgery.

The pivotal Phase IIb/III, multicentre, randomised, open-controlled study will determine the efficacy and safety of PREOB® in the treatment of hypotrophic non-union fractures of long bones. PREOB® will be compared to bone autograft in a non-inferiority design including a 12 month follow-up. 176 patients will be randomized in two groups in a 1:1 ratio (88 patients in the PREOB® group vs. 88 patients in the bone autograft group).

Efficacy and safety will be checked at each scheduled visit over the 12 month follow-up period for all patients using clinical (i.e., pain and function) and radiological evaluation. An interim analysis is planned at the midpoint of the study.

Non-union is a serious fracture complication where the normal process of bone healing is interrupted. In general, if a fracture is still evident at six months post injury, it will remain unhealed without specific treatment. Current standard of care involves invasive surgeries with a high risk of complications. Bone Therapeutics' cell therapy product, PREOB®, could help treat 350,000 patients annually in Europe and North America alone.

PREOB® is also being evaluated in an ongoing Phase III trial for the treatment of osteonecrosis.

**Enrico Bastianelli, CEO of Bone Therapeutics commented**, "We are delighted to have started this pivotal trial of PREOB® for the treatment of non-union fractures, an area of significant unmet medical need. For Bone Therapeutics' to have two pivotal phase IIb/III trials running simultaneously is quite an achievement. Alongside our allogeneic product pipeline, today's trial start further strengthens our position as a regenerative therapies leader in the field of orthopaedics."

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company or, as appropriate, the Company directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking

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## 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 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 regenerative 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 as well as in a phase II trial for severe osteoporosis. Bone Therapeutics is also developing an allogeneic bone cell product, ALLOB®, which is in a phase II clinical trial for delayed union fractures. All of Bone Therapeutics' regenerative 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](http://bonetherapeutics.com)*

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