

## Bone Therapeutics' pivotal phase III osteonecrosis trial with PREOB<sup>®</sup> hits a new milestone

### 30 centres across Europe now active

Gosselies, Belgium, 7<sup>th</sup> November 2013 - **BONE THERAPEUTICS**, the regenerative therapy company addressing unmet needs in the field of orthopaedics via a minimally invasive approach, announces today that its phase III pivotal trial to treat osteonecrosis with its lead bone forming cell product PREOB<sup>®</sup> is actively running in 30 European centres.

Bone Therapeutics obtained clearance from the Competent Authorities to launch the pivotal phase III trial with PREOB<sup>®</sup> in osteonecrosis in 2012. Today, 30 centres across Belgium, Germany, France and the Netherlands are active and ready to recruit patients to assess the safety and efficacy of PREOB<sup>®</sup> in early stage osteonecrosis of the femoral head. Osteonecrosis is a rare disease affecting ~200,000 new patients each year in Europe and the USA. There is currently no treatment for osteonecrosis available.

PREOB<sup>®</sup> is a first-in-class autologous osteoblastic/bone forming cell product. PREOB<sup>®</sup> is positioned as a first-line treatment as it is administered via a minimally invasive approach directly into the necrotic lesion, thereby avoiding the need for open surgery. PREOB<sup>®</sup> has already acquired orphan drug status for the treatment of osteonecrosis in both Europe and the USA.

The phase III study will enrol 130 adult patients who will be randomized 1:1 and either receive a single administration of PREOB<sup>®</sup> or placebo into the necrotic lesion using a core decompression procedure. Efficacy and safety endpoints will be determined in all patients at each scheduled visit over the 24-month follow-up period using clinical (i.e., pain and function) and radiological evaluation.

**Enrico Bastianelli, CEO of Bone Therapeutics commented**, "We are very pleased with the progress of this pivotal phase III trial for our most advanced autologous product PREOB<sup>®</sup>. The significant interest we have seen from the centres so far reflects the excitement from the orthopaedic community in this unique approach."

## 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' lead product, PREOB<sup>®</sup>, 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 product, ALLOB<sup>®</sup>, 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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