

BONE THERAPEUTICS RECEIVES CLEARANCE FOR ITS PIVOTAL PHASE III OSTEONECROSIS TRIAL WITH PREOB[®] IN EUROPE AND TREATS THE FIRST PATIENTS IN THE STUDY

Key points:

- Bone Therapeutics' phase III trial submission cleared by the competent authorities in Europe. This clearance further validates Bone Therapeutics' clinical, regulatory, and manufacturing capabilities
- PREOB[®], Bone Therapeutics' first cell therapy product, has been shown in previous studies to halt or revert the progression of osteonecrosis for which there is no conservative treatment

Bone regenerative medicine company Bone Therapeutics announced today that after receiving clearance from the competent authorities in Europe, its PREOB[®] phase III pivotal trial to treat osteonecrosis has started with the first patients included in the study.

PREOB[®], a first-in-class second generation Advanced Therapy Medicinal Product (ATMP), is an autologous bone cell medicinal product administered percutaneously via a minimally invasive approach, avoiding the need for surgery. PREOB[®], being developed under an orphan drug designation granted both in Europe and in the USA, will be the first conservative treatment for this indication.

With over 200,000 new cases per annum in Europe and North America, osteonecrosis is a painful and devastating disorder of the hip, affecting young patients (30-50 years) and leading within 2 years to femoral head collapse and total hip replacement.

This pivotal phase III trial aims at reproducing the positive pilot trial results where the implantation of PREOB[®] has been shown to halt or revert the progression of the disease and to significantly improve pain and hip function in patients with early stage osteonecrosis, compared to the reference group. This trial is anticipated to be the last phase of testing before obtaining the approval for commercialization.

Bone Therapeutics' pivotal phase III trial: 20 to 25 centres in Europe, 130 patients with early stage osteonecrosis

Patients will be randomized to receive either PREOB[®] or a placebo in double-blind controlled study design. This trial will be the first double-blind pivotal trial of its class.

Supported by the Walloon Region and its investors, Bone Therapeutics' teams are achieving major steps in the Company's development. Bone Therapeutics' Chief Executive Officer, Dr. Enrico Bastianelli, comments: "We are particularly enthusiastic about the unique properties of our bone cell therapy product. This achievement underscores the strength and robustness of Bone Therapeutics' clinical, regulatory, manufacturing and research capabilities. It is a significant step in bringing adult derived-stem cell therapeutics closer to the market, and to patients suffering from severe, debilitating diseases. PREOB[®] will be our first cell therapy product commercialized in Europe."

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About Bone Therapeutics

Headquartered at the Biopôle of Gosselies (Wallonia, Belgium), Bone Therapeutics is a leading international biotechnology company specialized in the treatment of osteo-articular diseases using cell therapy. With its proprietary cell technology platform, the Company is developing innovative cell products for the repair and regeneration of bone and joint tissues. The Company's strategic position in skeletal tissue repair and regeneration is supported by an outstanding knowledge of the bone/joint physiology and pathophysiology in major diseases as well as in niche indications, the pioneering works of its founders in stem cell transplantation in humans and a long-standing expertise in cell therapy clinical trials and regulatory affairs. Bone Therapeutics has a large portfolio of cell therapy products including PREOB[®] currently in phase III pivotal trials in Europe, ALLOB[®] an allogeneic bone cell product and MXB, a matrix-embedded cell product. The Company works in collaboration with the rheumatology department of Hôpital Universitaire Erasme (ULB, Brussels, Belgium) and the rheumatology department of the Hôpital CHU Sart-Tilman (Ulg, Liège, Belgium).