Gosselies, Belgium, 7th 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®

is actively running in 30 European centres.

Bone Therapeutics obtained clearance from the Competent Authorities to launch the pivotal phase III trial with PREOB® 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® 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® is a first-in-class autologous osteoblastic/bone forming cell product. PREOB® 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®

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® 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®

. The significant interest we have seen from the centres so far reflects the excitement from the orthopaedic community in this unique approach."