Bone Therapeutics demonstrates superiority of PREOB® in Phase IIB osteonecrosis study presented at EULAR

- ***Statistically significant superiority of PREOB® over standard of care in osteonecrosis treatment***
- ***50% reduction in hip fracture risk***
- ***Significant reduction in hip pain (50%) and significant improvement of hip function (45%)***

Gosselies, Belgium, 8 June 2016 – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in the fields of bone fracture repair, fracture prevention and spinal fusion, today announces that it will present the complete set of data from the PREOB® Phase IIB osteonecrosis study at the Annual European Congress for Rheumatology (EULAR) in London from 8 to 11 June 2016. These data demonstrate the superiority of a single administration of PREOB® over standard of care in halting or reversing the progression of osteonecrosis of the hip.

The objective of this Phase IIB study was to evaluate the safety and efficacy of a single PREOB® administration in a randomized comparison with the current standard of care (bone marrow concentrate implantation[1] - BMC) in osteonecrosis of the hip. Out of 63 patients (hips) treated, 60 were assessable for efficacy analyses (n=30 PREOB®, n=30 BMC). The primary efficacy endpoint was the proportion of responders at 24 months, with responders defined as the absence of progression to fracture and a clinically significant pain improvement.

The results show that at 24 months, only 37% of patients (hips) in the standard of care group had responded to treatment versus 70% of the PREOB® group (*p=0.011*) and that the proportion of hips that progressed to fracture was reduced by 50% by PREOB® group versus standard of care. The same results were observed at 36 months. In terms of clinical improvement, which was measured using the WOMAC® pain scale [2] patients treated with PREOB® had a clinically relevant and statistically significant improvement in joint pain and function at all study time points (from 3 to 36 months), compared to no improvement in patients treated with the standard of care. Of reported adverse events, 2.7% were possibly related to the procedure or the cell therapy products[3]. These events are in accordance with the possible risks linked to study procedures (in particular bone marrow aspiration) as described in the literature.

Overall, this Phase IIB study demonstrates the superiority of PREOB® over standard of care in halting or reversing the progression of osteonecrosis of the hip. Prof. Valerie Gangji, Chief Medical Officer of Bone Therapeutics, will present these Phase IIB data in poster #THU0540 at EULAR on 9 June.[4] To access the poster, please visit the Bone Therapeutics website.

Enrico Bastianelli, Chief Executive Officer of Bone Therapeutics, commented: *"Presenting these data is a significant validation of our approach to this orphan disease, where patients are in desperate need of an effective treatment. These Phase IIB data show the long-term beneficial effects of PREOB® in relieving symptoms and halting or reversing the progression of the disease. PREOB® is currently being evaluated in a European Phase III trial for osteonecrosis and preparations are ongoing to launch a Phase III trial in the US and these data further increase our confidence in the positive outcome of this ongoing trial."*

[1] Implantation of PREOB® or of BMC occurs through a minimally invasive procedure called core decompression.
[2] The WOMAC® scale is a validated scale for hip pain and function.
[3] Of the 15 treatment-emergent adverse events, 8 occurred in the PREOB® group and 7 in the standard of care/BMC group.
[4] Poster THU0540 (available on the website), "Autologous osteoblastic cells (PREOB®) versus concentrated bone marrow implantation in osteonecrosis of the femoral head: A randomized, controlled, single-blind study", V. Gangji, M. Toungouz, C. Lechanteur, Y. Beguin, E. Baudoux, V. De Maertelaer, S. Pather, R. Katz, J. Ino, D. Egrise, M. Malaise, J.-P. Hauzeur, Rheumatology Dept, Hemobiology and Transfusion Dept, Hôpital Erasme, Brussels, Haematology and Laboratory of Cell Therapy, CHU Sart Tilman, Liège, Faculty of Medicine, Université Libre de Bruxelles, Radiology Dept, Hôpital Erasme, Brussels, Bone Therapeutics, Gosselies, Nuclear Medicine Dept, Hôpital Erasme, Brussels, Rheumatology Dept, CHU Sart Tilman, Liège, Belgium.

About PREOB®

PREOB® is Bone Therapeutics' first-in-class autologous osteoblastic cell therapy product that can be administered percutaneously via a minimally invasive approach, avoiding the need for open surgery. PREOB® is currently in two pivotal trials in Europe: a Phase III trial for the treatment of osteonecrosis and a Phase IIB/III trial for the treatment of long bone non-union fractures. PREOB® also showed positive preliminary results in a Phase IIA trial for the treatment of severe osteoporosis.

About osteonecrosis

Osteonecrosis of the hip is a painful disease characterized by the death of bone cells and the loss of the associated bone marrow elements, leading to articular collapse and joint destruction. The condition typically affects people between the ages of 30 and 50, for whom hip replacement is not an appropriate long-term solution due to the limited lifespan of prostheses. Generally, the disease leads to a total hip replacement in less than two years and this before the age of 40 in half of the patients. The exact cause of the disease is not known, however certain risk factors have been defined, such as corticosteroid therapy and alcohol abuse.

About Bone Therapeutics

Bone Therapeutics is a leading biotechnology company specializing in the development of cell therapy products intended for bone fracture repair and fracture prevention. The current standard of care in this field involves major surgeries and long recovery periods. To overcome these problems, Bone Therapeutics is developing a range of innovative regenerative products containing osteoblastic/bone-forming cells, administrable via a minimally invasive percutaneous technique; a unique proposition in the market.

PREOB®, Bone Therapeutics' autologous bone cell product, is currently in pivotal Phase IIB/III clinical studies for two indications: osteonecrosis and non-union fractures, and in Phase II for severe osteoporosis. ALLOB®, its allogeneic "off-the-shelf" bone cell product, is in Phase II for the treatment of delayed-union fractures and lumbar fusion for degenerative disease of the spine, including a minimally invasive therapy for failed spinal fusions. The Company also runs preclinical research programs and develops novel product candidates.

Founded in 2006, Bone Therapeutics is headquartered in Gosselies (South of Brussels, Belgium). Bone Therapeutics' regenerative products are manufactured to the highest GMP standards and are protected by a rich IP estate covering 11 patent families. Further information is available at: www.bonetherapeutics.com.

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