Press Release 22 June 2015

Bone Therapeutics reports first results of its Phase IIA trial for PREOB® in severe osteoporosis

Preliminary results show migration of intravenously injected cells to the bones and no treatment-related safety concerns reported in first patient cohort

Gosselies, Belgium, 22 June 2015 - BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE) the bone cell therapy company addressing high unmet medical needs in the field of bone fracture repair and bone fracture prevention, today announces the first results of its Phase IIA PREOB® osteoporosis trial.

Out of the eight patients enrolled, seven were treated in the first part of this Phase IIA trial, which aims to evaluate PREOB® in the treatment of osteoporosis patients who do not respond to anti-osteoporotic therapy[1]. Primary endpoints of the study are safety and biodistribution of PREOB® cells administered intravenously: homing of cells to the bones most prone to osteoporotic fractures is indeed the first condition for the therapy to have effect.

The biodistribution of radioactively-labelled PREOB® cells was followed during 72 hours using SPECT/CT[2] scan to determine their location in the body after intravenous administration. Follow-up of this first group of patients showed a progressive accumulation of PREOB® cells into the axial skeleton (i.e., vertebrae and pelvis) after injection. This outcome, which is necessary to support future efficacy results, could lead to clinical benefits for the patient. Importantly, no serious adverse events related to the treatment were reported.

In the study, patients with severe osteoporosis aged 40 to 85 years are treated by intravenous infusion of PREOB® to determine the fate of the osteoblastic cells after administration and their effect on clinical symptoms, on the occurrence of fractures and on bone turnover.

Osteoporosis is a condition characterized by an excessive loss of bone mass, leading to bone fragility and increased fracture risk. Osteoporosis is considered a serious public health concern and ageing demographics continue to increase the affected population. Current treatments for osteoporosis predominantly inhibit bone resorption, but do not actively stimulate bone formation, and up to one third of patients under treatment are still losing bone mass or experiencing fractures. The potential market of patients who do not respond adequately to treatment is around 10 million patients, or about a third of this $8 bn drug market[3] (growing at a 4-5% rate per year). With PREOB®, Bone Therapeutics aims to offer a new mechanism of action based on the administration of differentiated bone-forming cells that provide osteogenic, osteoclastic and angiogenic properties[4].

These positive safety data and biodistribution readings show progression towards the Company's goals in osteoporosis as outlined at the time of its Initial Public Offering in February.

Enrico Bastianelli, CEO of Bone Therapeutics, commented: *"In accordance with the clinical pipeline strategy outlined at the time of the IPO, we are delighted to share the first results from the PREOB® osteoporosis trial. Importantly, no treatment-related safety concerns have been reported for the first patient cohort, and the fact that we have shown that our intravenously administered osteoblast are reaching their target seems promising for the upcoming results."*

[1] Eight patients were enrolled in the study, of whom one did not meet the eligibility (i.e., inclusion & exclusion) criteria for participating into the study and was therefore not treated.
[2] A SPECT (single photon emission computed tomography) scan visualizes the radioactive label attached to the cells in order to determine their location in the body. This is combined with a CT scan, that visualizes anatomical structures using x-rays, to allow specification of the exact location.
[3] Transparency Market Research, Osteoporosis Drugs Market

[4] Osteoblastic = stimulating bone formation ; osteoclastic = stimulating bone resorption ; angiogenic = stimulating blood vessel formation

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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 I/IIA for the treatment of delayed-union fractures and lumbar fusion for degenerative disease of the spine. 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 9 patent families. Further information is available at www.bonetherapeutics.com.

For more information, please contact:

Bone Therapeutics SA	Tel: +32 (0)2 529 59 90
Enrico Bastianelli, Chief Executive Officer/ Wim Goemaere, Chief Financial Officer	investorrelations@bonetherapeutics.com
For Belgium and International Media Enquiries	
Consilium Strategic Communications	Tel: +44 (0) 20 3709 5701
Amber Bielecka, Jessica Hodgson, Lindsey Neville and Hendrik Thys	bonetherapeutics@consilium-comms.com
For French Media and Investor Enquiries	
NewCap Investor Relations & Financial Communications	Tel: + 33 (0)1 44 71 94 94
Pierre Laurent and Antoine Denry	bone@newcap.fr

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