

Bone Therapeutics to enhance value of its severe osteoporosis program by transitioning to allogeneic development

Recent encouraging efficacy data with PREOB[®] in osteoporosis combined with positive efficacy and safety data in other allogeneic programs supports new strategy

Gosselies, Belgium, 19 May 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 plans to commence a Phase II trial for the treatment of severe osteoporosis with its allogeneic “off the shelf”¹ bone cell therapy product, ALLOB[®].

Enrico Bastianelli, Chief Executive Officer of Bone Therapeutics, commented: *“Bone Therapeutics’ allogeneic product has several advantages with regards to dosing, logistics and scalability, which offer potential benefits for commercialisation in a larger patient population. Following encouraging preliminary data from the osteoporosis study with our autologous product PREOB[®], combined with promising efficacy and safety results obtained with ALLOB[®] in other studies, we believe investigating ALLOB’s potential in severe osteoporosis, instead of PREOB[®], could create a better solution for patients and enhance value creation from a partnership deal for this product.”*

Osteoporosis is a condition characterized by an excessive loss of bone mass due to impaired bone turnover. The natural balance between bone formation and bone resorption is disturbed, leading to bone fragility and increased fracture risk. The disease affects a large population of more than 30 million patients in Europe and the US, with the total market estimated to be worth up to \$8.4 billion, of which up to 30% does not respond to available therapies, so called “severe” osteoporosis.

The encouraging results of the first cohort of patients in the Phase IIA trial of PREOB[®] for severe osteoporosis demonstrated a sustained beneficial effect from a single intravenous PREOB[®] administration on pain and bone turnover markers. Additional biomarker analyses confirm the trends observed during the 12-month follow-up period. In an early phase, a decrease in bone resorption markers were observed, as well as a limited decrease in bone formation markers. In later phases, while bone resorption markers tend to re-increase, bone formation markers² show a progressive increase. Interestingly, the inhibitors of bone formation³ show a clear decrease up to 12 months. Overall, these preliminary data seem to indicate that bone resorption is reduced in the first months after PREOB[®] administration, while the formation of new bone is stimulated in later phases.

The preparation for the Phase II trial with ALLOB[®] for the treatment of severe osteoporosis has already started and the trial is expected to commence early in 2017.

In line with this announcement, the Company has updated its corporate presentation, available for download on the website: <http://www.bonetherapeutics.com/en/investors/presentations>.

¹ Allogeneic”, or “off the shelf” therapies are those in which the cells are harvested from healthy donors, as opposed to “autologous” where the cells come from the patient him/herself.

² Relevant bone-formation markers include CTX, B-ALP, P1NP, osteocalcin, IGFBP-1 and periostin.

³ Inhibitors of bone formation include SOST and IGFBP-7.

● About severe osteoporosis

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 (by altering osteoclast activity and lifespan) but do not actively stimulate bone formation, and up to one third of patients under treatment are still losing

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bone mass or experiencing fractures. Bone Therapeutics aims to offer a new mechanism of action to improve bone mass based on the administration of differentiated bone-forming cells.

● 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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