Press Release 12 November 2015

Bone Therapeutics' ALLOB® receives Orphan Drug Designation for Osteogenesis Imperfecta from the EMA and FDA

Gosselies, Belgium, 12 November 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 that its allogeneic bone cell therapy product, ALLOB®, received Orphan Drug Designation (ODD) from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) for the treatment of the genetic bone disorder osteogenesis imperfecta.

Osteogenesis imperfecta, also known as brittle bone disease, is a rare genetic disorder that causes bone fragility, fractures and deformities. The estimated prevalence for Europe and the US is 0.64 cases per 10,000 inhabitants.[1] The clinical outcome is very heterogeneous and can range from mild bone fragility to severe bone deformity with short stature and even to death in the most severe cases. Current treatments are limited; they include surgery and the use of bisphosphonates, two strategies that are often associated with severe complications. Consequently, these treatments fail to offer long-term solutions and fractures remain difficult to treat.

This orphan drug designation opens up the possibility for Bone Therapeutics to develop its allogeneic bone cell therapy product, ALLOB®, for the treatment of osteogenesis imperfecta. In this disorder, where the underlying cause is genetic, the allogeneic origin of the ALLOB® cells is a significant benefit. Bone-forming cells can be administered systemically or locally at the site of the fractures – which are generally difficult to treat in these patients – in order to improve structural integrity of the bone matrix by replacing the defective bone cells. Hence, ALLOB® could increase bone strength, decrease the risk of new fractures and accelerate fracture repair in these patients.

It has been nearly ten years since the US FDA granted an orphan drug designation in the field of osteogenesis imperfecta, while for Europe ALLOB® will be the first product to be granted the designation. By obtaining orphan drug designation, the Company will benefit from such incentives as market exclusivity in Europe (for ten years) and in the US (for seven years), once the medicine is approved for commercialisation. Furthermore, through the ODD scheme, the Company may benefit from significant fee reductions with respect to protocol development, scientific advice and product registration procedures. Previously, the Company received ODD for PREOB® and ALLOB® for the treatment of osteonecrosis.

Enrico Bastianelli, CEO of Bone Therapeutics, commented: *"We are delighted to have received orphan drug designation for ALLOB® in osteogenesis imperfecta, a debilitating disease affecting young people. Currently, we have not initiated clinical trials in this field, however, the orphan drug designation gives us the opportunity to further enhance our product portfolio in the future and develop a more effective treatment that, contrary to the available treatments, targets the cause of the disease."*

[1]Estimates based on population studies reporting the epidemiology of osteogenesis imperfecta in Europe (Andersen *et al*., 1989 Clin Genet 36:205-5; Donnelly *et al*., 2010 Ulster Med J 79:114-18; Heiberg 1983 Clin Genet 23:233; Kuurila *et al*., 2002 Ann Otol Rhinol Laryngol 111:939-46; Martin *et al*., 2007 Osteoporos Rep 5:91-7).

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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 spinal fusion procedures. 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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