

Bone Therapeutics completes recruitment of 16 patients in ALLOB[®] Phase I/IIA delayed-union study

Last patient for interim analysis treated end of February
Results interim data analysis expected in September 2017

Gosselies, Belgium, 9 March 2017, 7am CET – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in orthopaedics and bone diseases, today announces that it has completed the recruitment of the first 16 patients in its Phase I/IIA delayed-union study of its allogeneic cell therapy product ALLOB[®].

The ongoing Phase I/IIA study is a six-month open-label trial to evaluate the safety and efficacy of ALLOB[®] in the treatment of delayed-union fractures of long bones. The study is targeting the recruitment of 32 patients, but is flexible and could be stopped prematurely after a positive evaluation of the interim data analysis of the first 16 patients. To date, 16 patients with a fracture that has failed to consolidate after a minimum of three and a maximum of seven months, have received a single percutaneous administration of ALLOB[®] directly into the fracture site. Fracture healing of ALLOB[®]-treated patients is assessed using clinical (e.g. pain, weight bearing) and radiological evaluation. Initial results from the first 8 patients showed that more than 85% of the patients were responder according to the protocol.

Thomas Lienard, CEO of Bone Therapeutics, commented: *“The successful recruitment of 16 patients for the ALLOB[®] Phase I/IIA delayed-union study is an important milestone for the company. Positive interim results for this first set of 16 patients could allow us to stop the study early, and would further validate our allogeneic strategy and the potential benefits it can bring to patients. We are encouraged by the previously reported positive preliminary safety and efficacy results of the first eight patients and are looking forward to communicating on the results of the interim data analysis of all 16 patients in the second half of this year, following the completion of the six-month follow-up period.”*

● **About Bone Therapeutics**

Bone Therapeutics is a leading biotechnology company specializing in the development of cell therapy products intended for orthopaedics and bone diseases. 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. 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. The Company also runs preclinical research programs for the development of 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.

Regulated information

9 March 2017

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