

## Bone Therapeutics Awarded Manufacturing Authorisation and European Approval to Produce Allogeneic Bone Cell Therapy Products

**ALLOB<sup>®</sup> product manufacturing process now fully secured**

**Gosselies, Belgium, 25 March 2013 - BONE THERAPEUTICS**, the leading international biopharmaceutical company focused on innovative cell therapy products for the treatment of bone diseases, announces that it has been awarded both 'Tissue Establishment and 'GMP' Accreditation for the manufacturing of its ALLOB<sup>®</sup> allogeneic bone cell therapy product, being initially developed for the treatment of impaired fractures.

The Tissue Establishment (i.e., Intermediate Structure) Accreditation is a pre-requisite for the manufacture of allogeneic cell therapies, and will permit Bone Therapeutics to have enhanced control over the ALLOB<sup>®</sup> production line. Bone Therapeutics' Intermediate Structure will be able to process, preserve, store and distribute human tissues upon their release from LTCG, the Tissue Bank. Bone Therapeutics will work in collaboration with the LTCG, the accredited Tissue Bank from the CHU Sart-Tilman based in Liège, Belgium and headed up by Prof. Yves Beguin.

This approval further strengthens Bone Therapeutics' cell product manufacturing capabilities. In addition to the allogeneic platform, Bone Therapeutics has autologous 'Production Establishment Accreditation' and manufacturing authorisations, which enables the Company to work on PREOB<sup>®</sup>, its autologous bone cell product, and manage all product design, engineering, validation, production and quality assurance to the highest GMP standards.

**Enrico Bastianelli, Chief Executive Officer of Bone Therapeutics, commented:** "Being awarded with ALLOB<sup>®</sup> manufacturing authorization is great news for Bone Therapeutics. This recent accreditation follows an earlier Manufacturing Authorization for our lead product, PREOB<sup>®</sup> and we are delighted that we have the necessary approvals to enable the onward development of both products."

### About ALLOB<sup>®</sup>

ALLOB<sup>®</sup> is an allogeneic bone cell therapy entering phase IIa clinical trial. It has also the potential for systemic applications such as in osteogenesis imperfecta, a rare genetic bone disease characterized by bone fragility and fractures. The indication of fractures is attractive with respect to the size of this market and the important medical needs (i.e., 1 Mio patients/year) and the absence of competition. ALLOB<sup>®</sup> has the advantage of being both osteoblastic and allogeneic and has been classified as a tissue engineered product under the ATMP regulation 1394/2007EMA. ALLOB<sup>®</sup> is expected to have a first-line treatment positioning due to its minimally invasive percutaneous implantation approach (as opposed to current surgical approach).

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### About Bone Therapeutics

Bone Therapeutics is a leading international biopharmaceutical company focused on innovative cell therapy products for the treatment of bone diseases. Utilizing the Company's unique knowledge of the bone/joint physiology and long-standing expertise in cell therapy and cell transplantation, Bone Therapeutics has created a fully integrated business with an advanced product pipeline comprising novel bone cell products, tailored in-house production methods, and minimally invasive treatment techniques.

Bone Therapeutics' lead product, PREOB<sup>®</sup>, is an autologous bone cell product, currently in Phase III clinical trials for the treatment of osteonecrosis and non-union fractures. Bone Therapeutics is also developing an allogeneic bone cell therapy product, ALLOB<sup>®</sup>, which is expected to enter the clinic in 2013, and MXB, a combined cell-matrix product for the treatment of large bone defects, currently in preclinical development. All of Bone Therapeutics' cell therapy products are manufactured to the highest GMP standards and protected by a rich IP estate.

The bone disease and reconstruction market is one of the largest healthcare markets in the world, with more than 4 million procedures requiring bone grafts performed annually in Europe and the USA alone. Bone Therapeutics is operating in areas where demand for new products is high and competition is low. Founded in 2006, Bone Therapeutics is privately held and headquartered in Gosselies (south of Brussels), Belgium. Further information is available at: [bonetherapeutics.com](http://bonetherapeutics.com)

### About Tissue Banks in Belgium

Within Belgian legislation, there are three types of tissue establishments available regarding the procurement and handling of human tissues and cells. These are: **Tissue Banks**, which are only found within hospitals; they can work on both autologous and allogeneic products. **Production Establishments** are able to perform most operations related to the industrial manufacturing of advanced therapy medicinal products (ATMPs) without the need for a Tissue Bank, provided that such use is autologous. NB: Bone Therapeutics' has been awarded 'production establishment' accreditation, which enables the company to work on its PREOB<sup>®</sup> product from the harvesting step onwards. **Intermediate Structures** are permitted to work directly with a Tissue Bank to process, preserve, store and distribute cells and tissues for allogeneic use.

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