

Bone Therapeutics secures up to €16 million loan financing from the European Investment Bank to accelerate ongoing clinical and commercial development of innovative orthopedic treatments

The EIB financing to be used for Bone Therapeutics' allogeneic cell therapy platform ALLOB and potential commercialization of enhanced viscosupplement JTA-004

Gosselies, Belgium, 1 July 2021, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, today announces that it has signed a loan agreement of up to €16 million with the European Investment Bank (EIB).

The EIB financing will support and prepare Bone Therapeutics' lead asset, the enhanced viscosupplement JTA-004 for future regulatory approval and commercialization. JTA-004, is being evaluated in a registrational phase III clinical trial for the treatment of osteoarthritic pain in the knee. This is the most prevalent knee condition affecting an estimated 250 million patients world-wide. Topline results of this study are soon expected in the third quarter of 2021. Following a positive outcome of the study, Bone Therapeutics plans to submit a marketing authorization application to European regulatory authorities in the first half of 2022. Bone Therapeutics continues to engage with potential partners to develop and commercialize JTA-004 in Europe, US and Asia.

The EIB financing will also be used to accelerate the clinical development of ALLOB, Bone Therapeutics' scalable allogeneic cell therapy platform. ALLOB is currently being tested in a phase IIb study in patients with difficult-to-heal tibial fractures. Patient recruitment of this study is currently anticipated to be completed in H1 2022 and the planned top line results are expected in H2 2022.

“Bone Therapeutics is building towards a very important set of milestones, including moving towards potential regulatory approval and commercialization of a therapy for over 250 million patients, as well as continuing with clinical development of its allogeneic cell therapy platform ALLOB. In addition, we are building on our success in orthopedics and moving our formidable MSC capabilities to target wider indications. The support of a major European financial institution such as the EIB will be an additional important component to this activity,” said Jean-Luc Vandebroek, Chief Financial Officer, Bone Therapeutics. “This financing committed by the EIB will allow Bone Therapeutics to further advance the clinical development of its lead product candidates JTA-004 and ALLOB, further accelerating paths to approval and commercialization.”

The EIB loan financing will be disbursed in two tranches of €8 million each, subject to conditions precedent. The first tranche of €8 million will become available upon approval of the issuance of associated warrants by Bone Therapeutics' General Meetings before the end of August 2021. The second €8 million tranche will be released when specific clinical and commercial milestones have been achieved.

The loan facility will be in the form of a senior loan, repayable to the EIB in a single payment five years following the disbursement of each of the two tranches. The loan carries a fixed interest of 2% per year paid annually and a 3% capitalized interest.

The loan financing is further supplemented by an agreement to issue warrants to the EIB: 800,000 warrants will be issued with the disbursement of the first tranche and 500,000 warrants with the disbursement of the second tranche. Each warrant will give the holder the right to subscribe to one ordinary share of Bone Therapeutics at the subscription price of €0.01 and with an exercise price which will be equal to the minimum of the 30 day volume-weighted average price and the last closing price of Bone Therapeutics' shares at the date of the pricing. The warrants have a maturity of 10 years and become exercisable from the repayment date of the relevant tranche, subject to certain customary exceptions. The warrant agreement further includes an anti-dilution provision which could apply in case of change in Bone Therapeutics' share capital, including capital increases if they exceed €15 million in aggregate starting from the disbursement of the first tranche.

Specific terms applicable to the warrants associated with the EIB loans can be consulted following the publication of the convening notice of Extraordinary General Meetings in the Investor section of Bone Therapeutics' website.

About the EIB

The European Investment Bank (EIB) is the long-term lending institution of the European Union, owned by its Member States. It makes long-term finance available for sound investment in order to contribute towards EU policy goals.

About Bone Therapeutics

Bone Therapeutics is a leading biotech company focused on the development of innovative products to address high unmet needs in orthopedics and other diseases. The Company has a diversified portfolio of cell and biologic therapies at different stages ranging from pre-clinical programs in immunomodulation to mid-to-late stage clinical development for orthopedic conditions, targeting markets with large unmet medical needs and limited innovation.

Bone Therapeutics is developing an off-the-shelf next-generation improved viscosupplement, JTA-004, which is currently in Phase III development for the treatment of pain in knee osteoarthritis. Consisting of a unique combination of plasma proteins, hyaluronic acid - a natural component of knee synovial fluid, and a fast-acting analgesic, JTA-004 intends to provide added lubrication and protection to the cartilage of the arthritic joint and to alleviate osteoarthritic pain and inflammation. Positive Phase IIb efficacy results in patients with knee osteoarthritis showed a statistically significant improvement in pain relief compared to a leading viscosupplement.

Bone Therapeutics' core technology is based on its cutting-edge allogeneic cell therapy platform with differentiated bone marrow sourced Mesenchymal Stromal Cells (MSCs) which can be stored at the point of use in the hospital. Currently in pre-clinical development, BT-20, the most recent product candidate from this technology, targets inflammatory conditions, while the leading investigational medicinal product, ALLOB, represents a unique, proprietary approach to bone regeneration, which turns undifferentiated stromal cells from healthy donors into bone-forming cells. These cells are produced via the Bone Therapeutics' scalable manufacturing process. Following the CTA approval by regulatory authorities in Europe, the Company has initiated patient recruitment for the Phase IIb clinical trial with ALLOB in patients with difficult tibial fractures, using its optimized production process. ALLOB continues to be evaluated for other orthopedic indications including spinal fusion, osteotomy, maxillofacial and dental.

Bone Therapeutics' cell therapy products are manufactured to the highest GMP (Good Manufacturing Practices) standards and are protected by a broad IP (Intellectual Property) portfolio covering ten patent families as well as knowhow. The Company is based in the BioPark in Gosselies, Belgium. Further information is available at www.bonetherapeutics.com.

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