

Bone Therapeutics and Link Health sign a non-binding term sheet for the global rights of ALLOB

Link Health to be granted global rights for development, manufacturing and commercialization of ALLOB

Bone Therapeutics to receive R&D cost reimbursement, commercial milestone payments of up to €60 million in total and tiered royalties on net sales of up to 25% upon completion of final agreement

The two parties will immediately commence the drafting of a binding License Agreement

Gosselies, Belgium, 29 November 2021, 7am CET – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, and Link Health Pharma Co., Ltd (“Link Health”), today announce the signing of a non-binding term sheet for the global rights for ALLOB, Bone Therapeutics’ allogeneic bone cell therapy. Subject to the fulfillment of customary condition precedents, Bone Therapeutics and Link Health aim to complete the final agreement and to fully execute it by the end of 2021.

This new partnership is separate and independent from the existing license agreement signed on [October 5, 2020](#), for the rights to develop, manufacture and commercialize ALLOB in China for Pregene, and in Hong Kong, Macau, Singapore, Taiwan, Thailand and South Korea for Link Health.

Bone Therapeutics will continue to work closely in partnership with Link Health and Pregene on all development activities. Link Health will be responsible for all future development, including the ongoing ALLOB TF2 Phase IIb trial and costs related to development, process development (scale up) and manufacturing of ALLOB. The deal will have no immediate direct cash impact, other than support of all development costs, since no upfront payment is foreseen, however, Bone Therapeutics will receive commercial milestone payments of up to €60 million in total and tiered royalties on net sales of up to 25%.

“The existing collaboration between Bone Therapeutics, Link Health and Pregene for the development of ALLOB in Asia has progressed swiftly and fully in line with the anticipated schedule. Bone Therapeutics expanding its collaboration with Link Health will allow for the development and potential availability of ALLOB globally for the benefit of patients with high orthopedic unmet medical needs,” said Miguel Forte, MD, PhD, Chief Executive Officer of Bone Therapeutics. “This deal now enables Bone Therapeutics to concentrate resources and focus more fully on its iMSC platform. We are now utilizing our extensive cell therapy expertise to develop cell and gene therapy products that have strong anti-inflammatory and immunomodulatory properties, for the treatment of acute life-threatening diseases.”

“Link Health has now broadened its therapeutic portfolio to address orthopedic unmet medical needs, aiming to be a global leader in this area. We have already several assets in clinical trial and next generation drug-material combo will also part of our efforts. For ALLOB, we believe that the evidence that Bone Therapeutics has already generated supports its potential clinical value for patients in various indications including spinal fusion and difficult fractures.” said Yan Song, PhD, Chief Executive Officer of Link Health. “Our extended collaboration with Bone Therapeutics will further support the global development of ALLOB. This will enable us to progress in delivering novel disease modifying solution for unmet medical needs for orthopedic patients worldwide.”

ALLOB is currently being evaluated in a randomized, double-blind, placebo-controlled Phase IIb study in patients with high-risk tibial fractures. This study will assess and compare against placebo, in association with standard of care stabilization surgery, the potential for ALLOB to accelerate fracture healing after 3-months follow-up and prevent late-stage complications. ALLOB will be applied by a single percutaneous injection 24-96 hours post-definitive reduction surgery in patients with fresh tibial fractures at risk of delayed or non-union.

About ALLOB

ALLOB is Bone Therapeutics' off-the-shelf allogeneic cell therapy platform consisting of human allogeneic bone-forming cells derived from cultured bone marrow mesenchymal stromal cells (MSC) from healthy adult donors. To address critical factors for the development and commercialization of cell therapy products, Bone Therapeutics has established a proprietary, optimized production process that improves consistency, scalability, cost effectiveness and ease of use of ALLOB. This optimized production process significantly increases the production yield, generating thousands of doses per bone marrow donation. Additionally, the final ALLOB product is cryopreserved, enabling easy shipment and the capability to be stored at the point of care for easy clinical use. The process will therefore substantially improve product quality, reduce overall production costs, simplify supply chain logistics, increase patient accessibility and facilitate global commercialization. The Company has implemented the optimized production process to produce clinical batches for the ongoing Phase IIb clinical trial in patients with difficult-to-heal tibial fractures.

About Link Health Pharma Co., Ltd

Link Health is a leading Chinese pharmaceutical company based in Guangzhou, Southern China. Link Health has a well-established team with solid track records in Licensing and local development of innovative medicinal products in China and Asia-Pacific. By its fully controlled subsidiary BioBone BV, Link Health has created a pipeline including 8 assets for global development in orthopedics and pain management. Link Health has its own research laboratories and core technology to lead drug-materials combo research and lead in the disease modifying novel therapy for orthopedic complicated diseases. Link Health has full team to execute registration, clinical development, business and marketing in China, in several Asian territories and in Netherlands in the Europe.

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 therapies at different stages ranging from pre-clinical programs in immunomodulation to mid stage clinical development for orthopedic conditions, targeting markets with large unmet medical needs and limited innovation.

Bone Therapeutics' core technology is based on its cutting-edge allogeneic cell and gene 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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