

Bone Therapeutics to regain worldwide rights to ALLOB

Bone Therapeutics received a unilateral termination notice from Pregene

Link Health expressed continued interest in ALLOB

Bone Therapeutics to continue negotiating rights for ALLOB with Link Health and other partners

Mont-Saint-Guibert, Belgium, 7 October 2022, 8.15am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, today announces it will regain worldwide rights to its allogeneic, off-the-shelf, bone cell therapy platform ALLOB further to the unilateral termination notice received from Shenzhen Pregene Biopharma Co., Ltd. (“**Pregene**”).

On 5 October 2020, Bone Therapeutics Pregene and Link Health Pharma Co., Ltd (“**Link Health**”) signed an exclusive license agreement for the manufacturing, clinical development and commercialization of Bone Therapeutics’ allogeneic, off-the-shelf, bone cell therapy platform ALLOB in China (including Hong Kong and Macau), Taiwan, Singapore, South Korea, and Thailand (the “**Agreement**”).

Under the Agreement, Bone Therapeutics was eligible to receive up to €55 million in development, regulatory and commercial milestone payments including €10 million in upfront and milestone payments anticipated in the first 24 months. Bone Therapeutics was also entitled to receive tiered double-digit royalties on annual net sales of ALLOB. Bone Therapeutics retained development and commercialization rights to ALLOB in all other geographies outside of those covered by this Agreement.

In November 2021, Bone Therapeutics signed a non-binding term sheet for the global rights for ALLOB, with its Chinese partners. The unilateral termination notified by Pregene will terminate the discussions with them and require further analysis from both Bone Therapeutics and Link Health. In the meantime, Bone Therapeutics will regain all development manufacture and commercialization rights of ALLOB worldwide.

Link Health, which was granted rights in Hong Kong, Macau, Taiwan, Singapore, South Korea, and Thailand, has expressed continued interest in ALLOB and is willing to pursue the collaboration with Bone Therapeutics. Bone Therapeutics and Link Health are in active discussions to precise the terms and scope of their collaboration.

Bone Therapeutics regaining all development manufacture and commercialization rights of ALLOB from Pregene will also entitle Bone Therapeutics to negotiate rights for ALLOB with, LinkHealth, and other partners.

Pregene's termination is, according to Pregene written communication, "necessitated by [alleged] regulatory reasons that due to the [purported] introduction of new laws and regulations, projects involving foreign human cell and related clinical trials will be, prohibited [in the future] in mainland China". Bone Therapeutics has not yet been in a position to confirm the veracity of this statement. Pregene shall transfer data to Bone Therapeutics and not participate in any future development or commercialization activities for the product.

*"Regain ownership of our product worldwide will provide us with the ability to capitalize on a broad range of strategic opportunities, including the re-licensing of ALLOB to a trusted partner that is committed to its development and commercialization", said **Jean Stéphenne, Chairman of Bone Therapeutics**.*

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. Currently **Bone Therapeutics** is concentrating specifically on the development of its most advanced clinical asset, the allogeneic cell therapy platform, **ALLOB**.

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. Its 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 Louvain-la-Neuve Science Park in Mont-Saint-Guibert, Belgium. Further information is available at www.bonetherapeutics.com.

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