

Bone Therapeutics introduces bone cell therapy platform in China & Southeast Asia

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Bone Therapeutics, the cell therapy company based in Belgium addressing unmet medical needs in orthopedics and other diseases, Link Health Pharma Co., Ltd in China and Shenzhen Pregene Biopharma Company have announced the signing of 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.

Under the agreement, Bone Therapeutics is 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 next 24 months.

Bone Therapeutics is also entitled to receive tiered double-digit royalties on annual net sales of ALLOB. Bone Therapeutics retains development and commercialization rights to ALLOB in all other geographies outside of those covered by this agreement.

As a result, Bone Therapeutics will continue to concentrate on its development and commercialization plans for ALLOB in the US and Europe and novel innovative cell-based products globally.

The agreement grants Link Health and Pregene exclusive rights to clinically develop and commercialize ALLOB for the treatment of human bone disorders in Greater China, Taiwan, Singapore, South Korea, and Thailand.

All rights for China will be transferred to Pregene and Link Health will gain rights for the remaining countries Bone Therapeutics will share its patented proprietary manufacturing expertise for the expansion and differentiation of bone-forming cells and has the option to sell clinical supplies to Link Health and Pregene in preparation for their clinical development of ALLOB.

ALLOB, an allogeneic and off-the-shelf cell therapy product manufactured through a proprietary, scalable production process, consists of human bone-forming cells derived from cultured bone marrow mesenchymal stem cells of healthy adult donors. In preclinical studies ALLOB has shown to reduce healing time in a delayed-union fracture model by half, and has demonstrated good tolerability and signs of efficacy in two Phase IIa studies for two separate indications. The Company's randomized, placebo-controlled, double-blind Phase IIb clinical trial in patients with difficult tibial fractures has received approval from regulatory authorities in six of the seven planned European countries to date, and is expected to enroll the first patient later this year.