News

Bone Therapeutics appoints Anne Leselbaum, MD as Chief Medical Officer

Bone Therapeutics (Euronext Brussels and Paris: BOTHE), the cell therapy company addressing unmet medical needs in orthopedics and other diseases, announced it has appointed Anne Leselbaum, MD as Chief Medical Officer (CMO), effective 23 August 2021.

As CMO, Dr. Leselbaum will take responsibility for the leadership of all clinical development and medical affairs strategies and activities across the entire Bone Therapeutics' pipeline and will oversee the regulatory interactions as Bone Therapeutics' clinical assets JTA-004 and ALLOB are moving through clinical development towards commercialisation.

"Bone Therapeutics is now at a critical time in its evolution as we are approaching the pivotal phase III clinical trial results of our lead asset, the enhanced viscosupplement JTA-004, for the treatment of osteoarthritic pain in the knee. We are also accelerating the clinical development of ALLOB, Bone Therapeutics' scalable allogeneic cell therapy platform. In addition, we are building on our success in orthopedics and moving our formidable Mesenchymal stromal cell (MSC) capabilities to target wider indications. These developments make it even more important for Bone Therapeutics to have a CMO with the experience to match our recently appointed CSO," said Miguel Forte, CEO, Bone Therapeutics. "Anne Leselbaum has extensive professional experience in bringing advanced therapeutics through the clinical stage to marketing authorization. This includes her experience with Takeda's approved allogeneic cell therapy product, Alofisel. In addition to her experience of building strong connections with key opinion leaders, her interactions and existing relationships with regulators, specifically the EMA and FDA will also be vital at this stage."

Bone Therapeutics has selected Dr. Leselbaum as CMO from her three decades of experience in strategic international clinical development, clinical operations and medical affairs. She has directly managed more than 10 clinical studies (from phase I to III) involving more than 3 500 patients and 350 sites in Europe, Americas and Asia-Oceania regions. She has also led clinical and regulatory interactions with both EMA and FDA. This includes for a number of products including vaccines and cell therapies, from pre-Investigational New Drug (IND) activity up to the filing of Marketing Authorization Applications (MAA).

"Bone Therapeutics now has an imminent potential regulatory approval and commercialization of an osteoarthritic therapy for over 250 Mio. patients. It is also continuing with clinical development of its allogeneic cell therapy platform ALLOB, and using its considerable MSC experience to target wider indications outside orthopedics," said Anne Leselbaum, MD, Chief Medical Officer of Bone Therapeutics. "Whilst the cell and gene therapy sector continues to develop, joining Bone Therapeutics, which is seeking to commercialize one therapy whilst moving into whole new areas of cutting edge research and clinical development is an excellent opportunity. I look forward to combining my experience with that of Bone Therapeutics' senior team to drive its therapies to patients of a range of therapies with few alternative options."

Dr. Leselbaum was most recently Vice President Clinical Development at Aelix Therapeutics. leading the clinical development of novel HIV vaccines. Prior to this, Dr. Leselbaum was Director Clinical Development at Tigenix, which was acquired by Takeda for more than half a bn. Euro. She was responsible for the development and implementation of clinical development of the allogeneic cell therapy product, Alofisel, for the treatment of complex perianal fistulas in Crohn's disease. She has also held leadership positions at the international pharmaceutical companies Almirall and Ipsen. Dr. Leselbaum received her Medical Degree from Paris Rene Descartes (Paris V), France.

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 10 patent families as well as knowhow. The Company is based in the BioPark in Gosselies, Belgium.

Further Information:

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