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Bone Therapeutics announces expansion of its pipeline supported by funding from the Walloon Region

Expansion of the pipeline from orthopedics into inflammatory conditions, including COVID-19, leveraging Bone Therapeutics platform of differentiated MSCs

Gosselies, Belgium, 20 August 2020, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the cell therapy company established in addressing high unmet medical needs in orthopedics and bone diseases, today announces it has received EUR 0.6 million in grants from the Walloon Region (Belgium) for research and initial preparatory steps towards clinical development of BT-20, its new allogeneic and off-the-shelf cell therapy product. Bone Therapeutics is now leveraging its expertise in Mesenchymal Stromal Cell (MSC) biology to expand its portfolio from orthopedics and bone diseases to inflammatory conditions.

MSCs and MSC derived cells have documented immunomodulatory and anti-inflammatory properties and several cell therapy approaches with MSC derived products are currently in development, or recently approved, for the treatment of multiple inflammatory conditions. Acute Respiratory Distress Syndrome (ARDS), an acute inflammatory lung condition with a high mortality rate or prolonged hospitalization, is frequent in severe cases of COVID-19. Despite several approaches in development, there are currently limited treatments for ARDS and current medical interventions are mostly limited to general care. Bone Therapeutics, in recognizing this high unmet medical need, initiated the development of BT-20 as the Bone Therapeutics' new allogeneic anti-inflammatory cell therapy product. BT-20 is produced using an adaptation of Bone Therapeutics' validated bone marrow derived MSC manufacturing platform and showed immunomodulating effects in in-vitro non-clinical studies.

The funding now received will help to continue further the pre-clinical development and the preparation of the submission of the Clinical Trial Application (CTA) for a phase I clinical trial of BT-20, for which Bone Therapeutics had already received initial Scientific Advice from the Belgian Federal Agency for Medicines and Health Products (FAMHP) in April

2020. The intended phase I clinical study would evaluate the therapeutic potential of BT-20 to improve COVID-19 ARDS patients' lung health and function and to reduce mortality. The study would be a controlled, randomized, double-blind of BT-20 versus placebo in addition to standard supportive treatments, in patients with moderate to severe COVID-19 related ARDS. Bone Therapeutics will consider the potential re-emergence of COVID-19 associated ARDS cases and the corresponding unmet medical need to decide the timing for the CTA submission for approval from the FAMHP, and subsequent conduct of the study, subject to securing the necessary financing.

"*Bone Therapeutics has built considerable expertise in MSCs and cell therapies for orthopedics and bone diseases. We are now at the stage where we can expand this expertise to a broader differentiated MSC based cell and gene therapy treatment portfolio, including inflammatory conditions,*" said **Miguel Forte, MD, PhD, Chief Executive Officer of Bone Therapeutics**. "*With the current global pandemic, there is an urgent need for therapies to tackle not just the immediate infection, but the critical and fatal inflammatory syndrome that COVID-19 causes. This represents our first anti-inflammatory target for our MSC platform with an opportunity to diversify into a broader range of additional inflammatory conditions in the future.*"

The non-dilutive funding was awarded by the Directorate of Research Projects of the Public Service of Wallonia for Economy, Employment and Research (SPW-EER) under the form of non-refundable grants within the framework of the "COVID 19" measure. The measure was launched by the Walloon Government and by Minister Willy Borsus, Vice-President of Wallonia and Minister of Economy, Research and Innovation, Digital Technology, Agriculture and Regional Planning. It has as aim to facilitate the implementation of research projects to combat the coronavirus and the COVID19 pandemic. The costs associated with the BT-20 program are not expected to change the current cash flow guidance as the funding now received will cover research and initial clinical preparation costs, with the next steps of the program, namely the conduct of the clinical study, being dependent on further funding.

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 both in research for immunomodulation and in 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 a@pproach to bone regeneration, which turns undifferentiated stromal cells from healthy donors into bone-forming cells. These cells are produced via the proprietary, scalable Bone Therapeutics' manufacturing process. Following the CTA approval by regulatory authorities in Europe, the Company is ready to start 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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