

Bone Therapeutics Provides First Quarter 2019 Business Update

Phase II ALLOB Spinal Fusion results expected mid-June

Well-positioned to advance product pipeline into late-stage clinical development

Strengthened the executive management team with key positions

Gosselies, Belgium, 7 May 2019, 7am CEST – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in orthopaedics and bone diseases, today provides a business update for the first quarter ended 31 March 2019.

Thomas Lienard, Chief Executive Officer of Bone Therapeutics commented: *“We are well-positioned to support long term growth with ALLOB, our cutting-edge allogeneic cell therapy platform, as well as JTA-004, our innovative viscosupplement addressing unmet needs in osteoarthritis. We are on track to report the data from the Phase IIa ALLOB study in patients undergoing a spinal fusion procedure before the summer. Following the strong Phase IIa results with ALLOB in patients with delayed union fractures and JTA-004 to treat pain in patients with knee osteoarthritis, we are now preparing the start of two late-stage clinical programs for which we expect to file clinical trials applications later this year. Our competitive, scalable, proprietary cell therapy manufacturing process is now optimised and representative of future commercial scale. With the appointments of Olivier Godeaux as Chief Medical Officer and Benoit Moreaux as Chief Scientific and Technology Officer, we now have a leadership team in place to execute our growth strategy and we are looking forward to updating the market on the progress we make.”*

Corporate highlights

- Presented *in vitro* and *in vivo* data for ALLOB at the Annual Meeting of the Orthopaedic Research Society (ORS), demonstrating the potent osteogenic properties of ALLOB to promote direct bone-formation and to improve fracture healing in relevant models.
- Strengthened the executive management team with the appointments of Olivier Godeaux, MD, as Chief Medical Officer and Benoit Moreaux, PhD, as Chief Scientific and Technology Officer.

Financial highlights

- Achieved a regulatory milestone as part of its PREOB collaboration with Asahi Kasei, triggering a €1 million success fee. In parallel, Asahi Kasei and the Company are reviewing their options regarding the future of the PREOB licensing agreement, following termination of the PREOB study in osteonecrosis of the hip in Europe.
- Good cost and cash management will remain a key priority. The net cash burn for the full year 2019 is expected to be in the range of € 12-13 million. The Company anticipates having sufficient cash to carry out its business objectives until the end of 2019, taking into account the € 3.75 million to be received under the convertible bond programme.
- As a result, the Company ended the first quarter of 2019 with a cash balance of € 7.13 million.

Outlook for the remainder of 2019

- The Company expects to report in mid-June top line data from the Phase IIa study with ALLOB in patients undergoing a lumbar spinal fusion procedure.
- The company will participate to the Belgian Life Science day organised by Kepler Cheuvreux in collaboration with Belfius in Paris on 18 June.
- In the second half of 2019, the Company plans to submit a clinical trial application (CTA) with the regulatory authorities in Europe and the United States to allow the start of a Phase II/III clinical trial with ALLOB in patients with delayed-union fractures, using its proprietary, optimised production process.
- Also, in the second half of 2019, the Company plans to submit a CTA with the regulatory authorities in Europe and the United States for the Phase III programme with JTA-004 in patients with knee osteoarthritis.

● **About Bone Therapeutics**

Bone Therapeutics is a leading biotech company focused on the development of innovative products to address high unmet needs in orthopaedics and bone diseases. Based in Gosselies, Belgium, the Company has a broad, diversified portfolio of bone cell therapy and an innovative biological product in later-stage clinical development across a number of disease areas, which target markets with large unmet medical needs and limited innovation.

Bone Therapeutics' core technology is based on its allogeneic cell therapy platform (ALLOB) which uses a unique, proprietary approach to bone regeneration, which turns undifferentiated stem cells from healthy donors into bone-forming cells. These cells can be administered via a minimally invasive procedure, avoiding the need for invasive surgery, and are produced via a proprietary, cutting-edge manufacturing process.

The Company's ALLOB product pipeline includes a cell therapy product candidate that is expected to enter Phase II/III clinical development for the treatment of delayed-union fractures and a Phase II asset in patients undergoing a spinal fusion procedure. In addition, the Company is also developing an enhanced viscosupplement, JTA-004, which is expected to enter Phase III development for the treatment of pain in knee osteoarthritis.

Bone Therapeutics' cell therapy products are manufactured to the highest GMP standards and are protected by a broad IP portfolio covering nine patent families as well as knowhow. Further information is available at www.bonetherapeutics.com.

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Regulated information

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