

## Bone Therapeutics Reports Financial Results for the First Nine Months of 2019 and Provides Third Quarter 2019 Business Update

**Strong progress in regulatory and operational preparations to advance pipeline assets towards late-stage clinical development**

**Cash burn guidance reiterated**

**Gosselies, Belgium, 6 November 2019, 7am CET – BONE THERAPEUTICS** (Euronext Brussels and Paris: BOTHE), the leading biotech company focused on the development of innovative cell and biological therapies to address high unmet medical needs in orthopaedics and bone diseases, today reports its financial results for the first nine months of 2019 and provides a business update for the third quarter ended 30 September 2019.

**Thomas Lienard, Chief Executive Officer of Bone Therapeutics commented:** *“We are making strong progress across the entire business and we are now approaching key value inflection points. As we near the completion of the necessary regulatory and operational measures, including the successful production of clinical batches, we are fully prepared to start late-stage clinical development with our allogenic cell therapy product, ALLOB, in patients with difficult-to-heal fractures, and our enriched protein solution, JTA-004, in patients with knee osteoarthritis. With most preparations in place, we look forward to further executing on our strategy and to communicating the next milestones in the following months.”*

### Operational highlights - Q3 2019 to date

- The Company has obtained scientific advice from European regulatory authorities to support the submission of the clinical trial applications for the Phase IIb trial with its allogenic cell therapy product, ALLOB, and the Phase III trial with its enriched protein solution, JTA-004.
- The Company has also completed the search for clinical research organizations who will oversee the ALLOB and JTA clinical studies. Two global contract research organizations with extensive experience in conducting large orthopaedic clinical studies have been selected to run these late-stage clinical trials.
- The first clinical batches of ALLOB are now being produced and stored as a cryopreserved stock to be used in the upcoming Phase IIb clinical trial in patients with difficult-to-heal fractures.
- Clinical lots of JTA-004 have been successfully produced by Company's qualified contract manufacturer and are ready for use in the knee osteoarthritis Phase III study.
- Following a two-day site audit in October, the Belgian Federal Agency for Medicines and Health Products (FAMHP) extended the GMP (Good Manufacturing Practices) certification of Company's manufacturing site in Gosselies (Belgium), further validating the high production and quality standards of its allogenic cell therapy platform.

### Financial highlights - first nine months 2019 <sup>(1)</sup>

- Operating loss for the first nine months of 2019 amounted to € 8.10 million compared to € 8.96 million for the same period last year.

- Cash used in operating activities amounted to € 7.97 million for the first nine months of 2019, compared to € 10.47 million for the same period in 2018. The net decrease of € 2.05 million was mainly related to increased cash received from grants and licensing, and reduced clinical activities following the completion of the clinical trials.
- As a result, net cash at the end of September 2019 amounted to € 10.11 million.

### Outlook for the remainder of 2019

- The Company plans to submit a clinical trial application (CTA) with the regulatory authorities before year-end to initiate a Phase IIb clinical trial with ALLOB in patients with difficult-to-heal fractures, using its optimized production process.
- The Company also anticipates submitting a CTA with the regulatory authorities to start the Phase III study with its innovative off-the-shelf protein solution, JTA-004, for the treatment of pain in patients with knee osteoarthritis before the end of the year.
- The Company reiterates its previous guidance of a net cash use of € 12-13 million for the full year 2019.
- Management will attend the following upcoming investor and partnering conferences:
  - Bio-Europe (11-13 November, Hamburg, Germany)
  - Bryan, Garnier & Co European Healthcare Conference (12-13 November, Paris, France)
  - Finance Avenue (16 November, Brussels, Belgium)
  - BioCentury & Bayhelix China Healthcare Summit (18-20 November, Shanghai, China) as part of the Belgian Economic Mission to the People's Republic of China
  - LSX Investival Showcase 2019 (19 November, London, UK)
  - Jefferies Healthcare Conference (20-21 November, London, UK)

<sup>(1)</sup> Unaudited numbers

### ● 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 IIb clinical development for the treatment of difficult-to-heal fractures and a Phase II asset in patients undergoing a spinal fusion procedure. In addition, the Company is also developing an off-the-shelf protein solution, 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 (Good Manufacturing Practices) standards and are protected by a broad IP (Intellectual Property) portfolio covering ten patent families as well as knowhow. Further information is available at [www.bonetherapeutics.com](http://www.bonetherapeutics.com).*

## Regulated information

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