

## 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 allogeneic 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 allogeneic 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 allogeneic 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**

6 November 2019

**● For further information, please contact:****Bone Therapeutics SA**Thomas Lienard, Chief Executive Officer  
Jean-Luc Vandebroek, Chief Financial Officer

Tel: +32 (0) 71 12 10 00

[investorrelations@bonetherapeutics.com](mailto:investorrelations@bonetherapeutics.com)**For International Media Enquiries:****Consilium Strategic Communications**

Marieke Vermeersch

Tel: +44 (0) 20 3709 5701

[bonetherapeutics@consilium-comms.com](mailto:bonetherapeutics@consilium-comms.com)**For French Media and Investor Enquiries:****NewCap Investor Relations  
& Financial Communications**

Pierre Laurent, Louis-Victor Delouvrier and Arthur Rouillé

Tel: + 33 (0)1 44 71 94 94

[bone@newcap.eu](mailto:bone@newcap.eu)

---

*Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company or, as appropriate, the Company directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.*

---