

Bone Therapeutics announces 2020 business outlook and reports year-end 2019 cash position

Phase III study of JTA-004 in patients with knee osteoarthritis on track to start patient enrollment early 2020

CTA submission initiated for Phase IIb with ALLOB in difficult tibial fractures

Two-year follow-up Phase IIa data for ALLOB in spinal fusion expected in H2 2020

Cash burn for the full year 2019 below guidance

Gosselies, Belgium, 22 January 2020, 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 orthopedics and bone diseases, today provides its business outlook for 2020 and reports its cash position for the year ending December 31, 2019.

Outlook for 2020

Clinical Trial Application (CTA) for the knee osteoarthritis pivotal Phase III study with the Company's enriched protein solution, JTA-004, has been submitted to regulatory authorities in 5 European countries and Hong Kong Special Administrative Region, with patient enrollment expected to start early 2020. The JTA-004 Phase III study is a placebo and active-controlled, randomized, double-blind study to evaluate the potential of a single, intra-articular injection of JTA-004 to reduce osteoarthritic pain in the knee compared to placebo or Hylan G-F 20, the leading osteoarthritis treatment on the market. The first results of the study are anticipated in the second quarter of 2021 after a follow-up period of 3 months.

The Company is initiating the CTA submission process in Europe for a Phase IIb clinical trial with its allogeneic bone cell therapy product, ALLOB, in patients with tibial fractures at risk for delayed healing, using its optimized production process. The first patients are expected to be enrolled in Q2 2020.

In the second half of 2020, the Company expects to report results from the 2-year follow-up period of the Phase IIa study with ALLOB in patients undergoing a spinal fusion procedure following the successful completion of the 12-months period for which positive results were published in July 2019. These results demonstrated that ALLOB in addition to the standard of care procedure was well-tolerated and resulted in significant clinical and radiological improvements.

Miguel Forte, Chief Executive Officer of Bone Therapeutics commented: *"I am very pleased to see that we continue to make strong progress in executing on our business strategy to become a global innovator in bone related diseases. In the next coming months, we expect to run a pivotal trial with our novel protein solution, JTA-004, with the goal to provide relevant regulatory and clinical evidence about the potential of JTA-004 as a treatment option for the many patients suffering from knee osteoarthritic pain. The anticipated start of the Phase IIb study in patients with difficult to heal fractures and the 24-months results from the Phase IIa trial in patients undergoing a spinal fusion procedure, which we expect later this year, could further underscore the unique potential of ALLOB to bring much needed innovation to the treatment of severe bone disorders."*

Cash position for the full year ended December 31, 2019

The continued strong focus on cash management resulted in a net cash utilization of €11.5 million⁽¹⁾ for the full year 2019 which was below the Company's guidance of €12-13 million. The net cash position totaled €8.6 million⁽¹⁾ for the year ended December 31, 2019. The Company anticipates having sufficient cash to carry out its business objectives into Q3 2020.

Following the previously announced discontinuation of the autologous cell therapy program, PREOB, end 2018, Asahi Kasei and the Company agreed to formally end the PREOB licensing agreement. As a result, Bone Therapeutics and the Walloon Region agreed to terminate the related reimbursable grant agreements under the form of Recoverable Cash Advances, thereby reducing cash reimbursements and associated interest payments that were due by the Company by € 1.4M over the next 5 years.

Financial Calendar 2020

- 11 March – Full Year Results 2019
- 29 April – Annual Report 2019
- 6 May – Q1 2020 Business and Financial Highlights
- 10 June – Annual General Meeting 2020
- 26 August – Half Year Results 2020
- 28 October – Q3 2020 Business and Financial Highlights

The financial calendar is communicated on an indicative basis and may be subject to change.

⁽¹⁾ Unaudited number

● 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 bone diseases. The Company has a broad, diversified portfolio of bone cell therapies and an innovative biological product in later-stage clinical development, which target markets with large unmet medical needs and limited innovation.

Bone Therapeutics is developing an off-the-shelf protein solution, JTA-004, which is entering Phase III development for the treatment of pain in knee osteoarthritis. Positive Phase IIb efficacy results in patients with knee osteoarthritis showed a statistically significant improvement in pain relief compared to a leading viscosupplement. The clinical trial application (CTA) to start the pivotal Phase III program has been submitted to the regulatory authorities in Europe and the trial is expected to start in Q1 2020.

Bone Therapeutics' other core technology is based on its cutting-edge allogeneic cell therapy platform (ALLOB) which can be stored at the point of use in the hospital, and 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, scalable cutting-edge manufacturing process. Following the promising Phase IIa efficacy and safety results for ALLOB, the Company has started the CTA submission procedure with the regulatory authorities in Europe to start the Phase IIb clinical trial with ALLOB in patients with difficult-to-heal fractures, using its optimized production process.

The ALLOB platform technology has multiple applications and will continue to be evaluated in other indications including spinal fusion, osteotomy and maxillofacial and dental applications.

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.

Regulated information

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● For further information, please contact:**Bone Therapeutics SA**Miguel Forte, MD, PhD, Chief Executive Officer
Jean-Luc Vandebroek, Chief Financial Officer

Tel: +32 (0) 71 12 10 00

investorrelations@bonetherapeutics.com**For International Media Enquiries:****Consilium Strategic Communications**

Marieke Vermeersch

Tel: +44 (0) 20 3709 5701

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

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