Bone Therapeutics announces 2019 business outlook and reports year-end 2018 cash position

Phase IIA results with ALLOB in patients undergoing a spinal fusion procedure expected mid-2019

CTA submission planned in H2 2019 to start delayed-union fractures study with ALLOB

Phase III study with JTA-004 in patients with knee osteoarthritis expected to start in H2 2019

Cash burn for the full year 2018 below guidance

Gosselies, Belgium, 22 January 2019, 7am CET – BONE THERAPEUTICS (Euronext Brussels and Paris: BOTHE), the bone cell therapy company addressing high unmet medical needs in orthopaedics and bone diseases, today provides its business outlook for 2019 and reports its cash position for the year ending December 31, 2018.

Outlook for 2019

The Company is on track to report top line data in mid-2019 from the Phase IIA study with its off-the-shelf, allogeneic bone cell therapy, ALLOB, in 32 patients undergoing a spinal fusion procedure.

In H2 2019, the Company plans to submit a clinical trial application (CTA) with the regulatory authorities in Europe to allow the start of a study with ALLOB in patients with delayed-union fractures, using its proprietary, optimised production process. The Company is currently generating the non-clinical data package as required.

The Company expects to submit a CTA with the regulatory authorities and to start the Phase III programme with the enhanced viscosupplement JTA-004, in patients with knee osteoarthritis, in H2 2019.

"*We're delighted with the continued clinical momentum of ALLOB and are further advancing this programme towards commercialization, supported by*

our new optimized manufacturing process," **said Thomas Lienard, Chief Executive Officer of Bone Therapeutics.** "*Our focus is now on progressing the late-stage clinical development of the ALLOB platform in delayed-union fractures and JTA-004 in osteoarthritis of the knee. We believe we have a compelling portfolio of programmes with the potential to provide best-in-class solutions to orthopaedics and bone diseases, and we look forward to updating on the progress of these programmes.*"

Cash position for the full year ended December 31, 2018

Strong focus on cash management and resource allocation optimization resulted in a cash utilization of €13.9 million(1) for the full year 2018 which was below the Company's guidance. As a result, the net cash position totalled €8.2 million(1) for the year ended December 31, 2018.

Subsequently, in January 2019, Bone Therapeutics received a €1 million milestone payment from licensee Asahi Kasei, after reaching a regulatory milestone following a consultation with the Japanese Regulatory Authority for PREOB. In parallel, Asahi Kasei and the Company are reviewing their options with regards to the future of the PREOB licensing agreement, following termination of the PREOB study in osteonecrosis of the hip.

Therefore, the Company anticipates having sufficient cash to carry out its business objectives into Q4 2019.

(1) Unaudited number

Financial Calendar 2019

- 25 April – Full Year Results 2018 and Annual Report 2018
- 7 May – Q1 2019 Business and Financial Highlights
- 12 June – Annual General Meeting 2019
- 30 August – Half Year Results 2019
- 6 November – Q3 2019 Business and Financial Highlights

Calendar may be subject to change and is communicated on an indicative basis.

ABOUT BONE THERAPEUTICS

About Bone Therapeutics

Bone Therapeutics is a leading cell therapy company addressing high unmet needs in orthopaedics and bone diseases. Based in Gosselies, Belgium, the Company has a broad, diversified portfolio of bone cell therapy products in clinical development across a number of disease areas targeting markets with large unmet medical needs and limited innovation.

Bone Therapeutics' technology is based on a unique, proprietary approach to bone regeneration, which turns undifferentiated stem cells into bone-forming cells. These cells can be administered via a minimally invasive procedure, avoiding the need for invasive surgery.

The Company's primary clinical focus is ALLOB, an allogeneic "off-the-shelf" cell therapy product derived from stem cells of healthy donors, which is in Phase II studies for the treatment of delayed-union fractures and spinal fusion. In addition, the Company also has an autologous bone cell therapy product, PREOB, obtained from patient's own bone marrow and currently in Phase III development for osteonecrosis of the hip, and JTA-004, a viscosupplement in development for the treatment of knee osteoarthritis. Bone Therapeutics' cell therapy products are manufactured to the highest GMP standards and are protected by a rich IP estate covering nine patent families. Further information is available at: www.bonetherapeutics.com.