

Bone Therapeutics Provides First Quarter 2020 Business Update

Strong progress in regulatory and operational preparations to start mid/late-stage clinical studies of company's advance pipeline assets

A total of €11 million financing secured, further strengthening cash position

Gosselies, Belgium, 6 May 2020, 7am CEST – 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 provides a business update for the first quarter ended 31 March 2020.

“Bone Therapeutics has experienced an excellent start to 2020, despite the COVID-19 pandemic,” said Miguel Forte, MD, PhD, Chief Executive Officer of Bone Therapeutics. “We have gathered regulatory approvals for the start of the next clinical trials of both JTA-004, Bone Therapeutics’ enriched protein solution, in patients with knee osteoarthritis and ALLOB, Bone Therapeutics’ allogenic cell therapy product in patients with difficult-to-heal fractures. As we have strengthened our cash position, Bone Therapeutics is now well prepared to advance both of its lead candidates through late-stage clinical development as soon as it is suitable to progress. Until then, we are fully focused on ensuring that when the trials go ahead, all precautions are taken for the safety of the nurses, physicians and patients involved in the studies. Together with our partners, we are taking the necessary health measures to conduct our clinical studies in compliance with the guidelines of the health agencies.”

Operational highlights – Q1 2020

- Bone Therapeutics has received regulatory approvals for its Clinical Trial Applications (CTA) for the next studies of both of its lead candidates. The pivotal phase III with the enriched protein solution, JTA-004, targeting osteoarthritic knee pain has now been approved by regulatory authorities in Belgium, Denmark, Moldavia and Hong Kong. The phase IIb study of its allogeneic cell therapy product, ALLOB, in patients with difficult tibial fractures, also received a first approval from Belgian regulatory authorities in March, ahead of schedule.
- The company appointed Stefanos Theoharis, PhD as Chief Business Officer (CBO), further strengthening its management team. Stefanos will be responsible for the company's corporate development activities and executing its business strategy.

Financial highlights – Q1 2020 ⁽¹⁾

- Net cash at the end of March 2020 amounted to €4.9 million.
- Good cost and cash management remains a key priority. The net cash burn for the full year 2020 is expected to be approximately €15.0 million. The increased expected net cash burn for FY2020 compared to FY2019 is mainly the result of increased clinical trial activities and costs associated with the JTA phase III and ALLOB phase IIb clinical studies. This assumes normal operation, as there may be further effects of the ongoing COVID-19 epidemic. Potential delay in patient recruitment in both studies could lower the expected cash burn and extend the anticipated cash runway further into 2021.

- Post period, Bone Therapeutics secured €11.0 million financing. This enables Bone Therapeutics to advance its key assets through mid/late stage clinical development. The financing operation consists of bridge loans, equity private placement by existing shareholders, and a private placement of convertible bonds (CBs) on an as-needed basis. The bridge loans are subject to obtaining a credit assurance, which is pending regulatory approvals expected in May 2020.
- As a result, the company anticipates having sufficient cash to carry out its business objectives into Q1 2021.

Outlook for the remainder of 2020 and COVID-19 impact on 2020-2021 guidance.

- Following the regulatory approvals, Bone Therapeutics is ready to initiate recruitment in the pivotal JTA-004 phase III clinical study targeting osteoarthritic knee pain and the ALLOB phase IIb study in patients with difficult tibial fractures, in the aforementioned countries. Due to the global COVID-19 pandemic, Bone Therapeutics has decided to decrease the recruitment activities of both studies to a minimum. This will support healthcare systems in the respective trial countries and enable them to concentrate on treating COVID-19 patients whilst necessary. As the evolution of the pandemic is uncertain and cannot be predicted at present, the studies may encounter a delay compared to the initial schedule. The situation in Europe and Hong Kong will be actively and closely monitored on an ongoing basis, and Bone Therapeutics plans to initiate the recruitment as soon as conditions allow.

The Chinese Special Administrative Region Hong Kong has been less severely affected by the COVID-19 pandemic and clinical centers in this area might be able to resume patient recruitments for the JTA-004 phase III trial before the summer.

In Europe, the COVID-19 epidemic seems to have passed its peak, as the number of infected people and hospitalized patients start to taper off, resulting in countries gradually lifting the lockdown measures. As the situation in the hospitals progressively normalizes, Bone Therapeutics expects to be able to reinstate clinical trial activities and patient recruitments for the JTA-004 phase III and ALLOB phase IIb studies in the European clinical centers during the summer and second half of 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.
- In the next few months, Bone Therapeutics plans to initiate the first discussions with the US FDA (Food and Drug Administration) in preparation of the next studies with ALLOB and JTA-004 in the large, important US market.
- Bone Therapeutics continues to engage discussions with potential partners to explore business opportunities. It also intends to prepare a fundraise in the second half of 2020, when favorable market conditions are met. Existing shareholders have already taken a pre-commitment to participate.

(1) 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 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) for the pivotal Phase III program has been approved by the relevant authorities allowing the start of the study.

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 CTA approval by the Belgian regulatory authority, the Company is ready to start the Phase IIb clinical trial with ALLOB in patients with difficult tibial 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.

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