

BBS-Bioactive Bone Substitutes Plc: The CE marking application of the Company's ARTEBONE® Paste product is in progress

07.08.2020

BBS-Bioactive Bone Substitutes Plc has received an offer and a draft contract concerning handling of application for CE marking of ARTEBONE® Paste product, company's ISO 13485 certification and related audits from Notified Body BSI (the Netherlands). The company has approved the offer and contract but the contract includes new requests of documents. The company is currently preparing these documents. Upon completion, the company is ready to submit technical documentation related to the application of CE marking to the Notified Body.

As part of the documentation to be submitted is the additional evidence of functionality of ARTEBONE® Paste required by the authority. Preliminary reports from the first and second follow-up time points have been received from the results of an animal experiment commissioned by the company last autumn. The results of the third and at the same time the last time point are still expected. According to the company's own opinion, the results are positive and they are capable of demonstrating the additional evidence. A change is still being made to the original way of measuring results, which will further refine the results already obtained.

CEO Ilkka Kangasniemi:

We are pleased that, in addition to dealing with the global corona pandemic, the authority has finally had time to respond to our call for tenders. Additionally, we are satisfied with the preliminary results of the animal experiment. After further measurements, the results are presumably valid to demonstrate the additional screen requirement that the authority has requested of us. For now, we are not changing the time table of the CE marking process. The possible effects of the additional document requirements and the specification of the method of measuring the results of the animal experiment on the schedule will be investigated and, if necessary, more information will be released during the autumn.

BBS-BIOACTIVE BONE SUBSTITUTES PLC

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This is information that BBS-Bioactive Bone Substitutes Plc is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above on 7 August 2020 at 12:00 am (UTC +3.00).

About BBS

BBS-Bioactive Bone Substitutes Plc is a Finnish orthobiologic biotech company. We have developed a new product for healing of difficult bone fractures and for solving the problems in bone healing. Our mission is to offer new generation medicinal products for the orthopedic surgery. The research and development in the field of medicine requires perseverance and courage to develop new things. We have over 20 years of expertise in this. Our operations are characterised by top expertise, innovativeness and dedicated and committed employees. The first product, ARTEBONE® paste, is ready and the application process for the CE-marking enabling commercialization is in progress.

More information: www.bbs-artebone.fi.

BBS-Bioactive Bone Substitutes Plc shares are listed on the Nasdaq First North Growth Market Finland and Nasdaq First North Growth Market Sweden. The company's Certified Adviser is Stockholm Certified Advisers AB, p. +46 70 5516 729, info@certifiedadviser.se