BBS-Bioactive Bone Substitutes Plc: ARTEBONE®’s CE process summary

BBS-Bioactive Bone Substitutes Plc | Company Release | August 16, 2024 at 09:30:00 EEST

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ARTEBONE® is a next-generation bone substitute product. Its CE approval process has been communicated through individual separate announcements, and the overall process or its stages have not been described in summary. This announcement has been prepared to address the aforementioned deficiency.

ARTEBONE® has had a complex and challenging approval process. It is a new and innovative bone substitute, which is always considered risky from the authorities’ perspective, and proving its functionality is also more laborious than for a simpler product. At the beginning of product development, the authority classified ARTEBONE® as a medicinal product due to its bone protein extract content, so product development was advanced as a medicinal product for about 5 years. However, it turned out that obtaining funding for a Finnish company located in a remote area for drug development was challenging, and hundreds of millions of extra funds would have been needed. Furthermore, it became apparent that ARTEBONE® might be approved as a medical device. Numerous negotiations were held with the authorities on this issue, which eventually accepted this alternative product registration route. However, the authorities did not have guidance for classifying a product combining a medical device and a drug. The aforementioned classification guidance was only received in 2018 from the European Commission concerning products on the borderline between a medical device and a drug (Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices, Version 1.19 (04-2018) 4.22), where ARTEBONE® is described as an example of a combination of osteoconductive ceramic (TCP) and osteoinductive medicinal substance. It also describes how ARTEBONE® can be approved in the medical device class III, which is the route the company has followed in registration.

In March 2022, the background work was completed, and the CE mark application documentation (European marketing authorization application) was submitted to the medical device evaluator (BSI) located in Amsterdam. The submission of the marketing authorization application took place at a time when there had been a significant change in the approval bureaucracy with the new regulation MDR 2017/745 for medical devices coming into force. All old products also had to seek approval under the new regulation, causing massive backlogs for the authorities, also prolonging the approval process for ARTEBONE®. The official classification decision was received in May 2023, confirming the company’s vision of ARTEBONE®'s product classification in medical device class III.

The first phase of the ISO 13485 quality management system inspection, which covers product manufacturing and ensures patient safety, i.e., the pre-inspection, began in November 2022. A separate microbiological inspection was held in February 2023, and the final inspection of the microbiological section was conducted in January 2024. Extensive phase 2 inspections began in March 2023, and the final inspection was conducted in August 2023. Fimea’s GMP inspection (“Good Manufacturing Practice”; a standard compliant with pharmaceutical industry quality requirements) took place in May 2023.

The quality system certificate was obtained in November 2023. The GMP certificate from Fimea, i.e., the pharmaceutical manufacturing license, was extended in June 2023. The certificates require continuous periodic inspections every 1–3 years.

ARTEBONE® contains all three levels of product approval difficulty; it is new and innovative, it contains an animal-derived component, and it also includes a medicinal component. Therefore, the approval process is significantly more challenging and time-consuming than for a simple medical product. For example, the approval of ARTEBONE® requires an inspection by the medicinal authority and an evaluation of the clinical trial for the medicinal component, which began in November 2023. Additionally, the EDQM (European Directorate for the Quality of Medicines & HealthCare) conducts an assessment of the safety and benefit of the animal-derived component.

Currently, the authorities and BBS are working on the evaluation of the technical documents. We believe we have been able to meet all the authorities' requirements regarding the product's functionality and safety, both in animal tests and in the clinical trial. We expect the CE mark soon, once the authority has completed its work. We cannot provide an exact timeline, as the authority takes its time and does not provide schedule forecasts.

The competitive situation for ARTEBONE® remains good. There is only one competitor on the market that applies a similar innovation, which includes a protein component in addition to TCP. This setup was the starting point for the development of ARTEBONE®. We aimed to create a bone substitute that closely resembles natural bone, which is achieved in the ARTEBONE® product. Unlike all competitors, the ARTEBONE® product combines both an osteoinductive component, which initiates bone formation, and an osteoconductive component, which serves as a platform for bone formation. The majority of competing products contain only one component.

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BBS in brief

BBS -Bioactive Bone Substitutes Plc is an orthobiology company that started its operations in 2003. We have developed a new product for the treatment of complex bone fractures and bone healing issues. Our goal is to provide next-generation medical products for the treatment of bone injuries in orthopedic surgery. In the pharmaceutical industry, the development and research work require perseverance and courage to innovate. We have a track record of over 20 years in this field. Our company is characterized by expertise, innovation, and dedicated employees who are passionate about their work. Our first developed product, ARTEBONE® Paste, is in the final stages of the CE marking process to enable its commercialization in the EU market. We are based in Oulu with a medical manufacturing facility in Reisjärvi, holding a manufacturing license. The company's headquarters are in Oulu, and we employ over 20 people.

BBS has been listed on Nasdaq First North Growth Market Finland since February 2018.

More information: www.bbs-artebone.fi