BBS-Bioactive Bone Substitutes Plc: We are pleased to announce that the clinical result of ARTEBONE® is positive yielding an outcome similar to patient's own bone graft

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The clinical investigation run by BBS-Bioactive Bone Substitutes Oyj in clinical centers in Finland and Poland has been finalized and reported. In this study ARTEBONE® paste was used as a bone void filler in fusions of ankle and subtalar joints. The results were compared to the literature references on autograft. Autograft, patients' own bone transplanted to the fusion site, is considered the gold standard. No synthetic substitute material has shown similar bone growth potential while keeping consistency and safety at high level.

The main result shows that the fusion rate with ARTEBONE® paste is comparable with the fusion rate with autograft (Myerson *et al.* 2019, DiGiovanni *et al.* 2013).

Equally important result is that ARTEBONE® paste showed no safety concerns or product related complications. It reduces the known risks and morbidity associated with both autograft and synthetic bone growth factor products.

ARTEBONE®, our next generation product, contains two main components of bone: mineral scaffold and bone proteins that promote bone growth. One major advantage of ARTEBONE® is that it is a ready-to-use product for bone problems in extremities, scapula and pelvis.

With the support of the results of the clinical study BBS-Bioactive Bone Substitutes Oyj expects to receive CE marking and to be able to start its commercial operations in European markets within a year. The company is aiming to start building its marketing and sales network starting in late spring.

Coordinating investigator Professor **Juhana Leppilahti** Oulu University Hospital, Finland:

This clinical investigation was a multi-centre, prospective study in subjects in need of a fusion of the ankle joint or subtalar joint to relieve persistent pain due to primary or secondary post-traumatic osteoarthritis. Safety was primarily determined by the incidence of unanticipated serious adverse device effects during follow-ups twelve months post-operatively. Performance was primarily determined by bone fusion rates assessed by computer tomography at six months and by sequential post-operative radiographs at all follow-up visits.

There were totally 34 patients in this study and five Investigation sites in Finland and Poland. Computer tomography at 6 months showed that the overall fusion rate in our study was 94% which is very good result in this kind of surgery.

These healing results are comparable to the results of autograft treatment found from the literature. Autografting has many side-effects. It requires an extra surgery to harvest bone from another site on the patient's own body. This second surgery damages healthy part of the body, causes long-lasting pain, increases risks of complication such as infection, delays recover, and thus increases costs.

The complications recorded in this study were in line with quality and quantity to those in the literature concerning ankle and hindfoot surgery.

The conclusion of this clinical investigation is that ARTEBONE® can be used in the treatment bone trauma and for filling bone voids or defects of the skeletal system such as extremities, scapula and pelvis.

Orthopedic surgeon **Timo Sirola** from University Hospital of Helsinki describes that BBS's new innovation is very easy to handle:

I have tested many different bone treatment materials during my career. Many products on the market are such that you have to do time-consuming mixing and preparation on the operating table before implantation but ARTEBONE® is in a ready-to-use syringe. It shortens time of surgical operation. Furthermore, the dose of the product is appropriate. The paste form makes it easy to deliver and apply to site of treatment. My opinion is that since the price of ARTEBONE® is on the same level with other premium synthetic products on the market, the promise that ARTEBONE® can replace autografting makes it particularly interesting.

CEO **Ilkka Kangasniemi**, BBS-Bioactive Bone Substitutes Oyj:

This clinical result is a very significant turning point in the company development as it shows how great potential ARTEBONE® has clinically and commercially. We have now first clinical evidence at hand showing that it is possible to replace autografting operations as the gold standard, with an off the shelf, ready to use, injectable product that performs equally well, however, without the complication risks associated with autograft or commercially available synthetic bone growth factors.

This ability has been well received by our clinical collaborators!

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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.com.

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