BONESUPPORT™ – First Patient Recruited in Study Evaluating CERAMENT® G and CERAMENT® V in Patients Undergoing Hip and Knee Arthroplasty Revisions

Lund, Sweden, 08:00 CEST 9 October 2017 – BONESUPPORT™, an emerging leader in innovative injectable bio-ceramic bone substitute products to treat bone voids caused by trauma, infection, disease or related surgery based on its unique CERAMENT® platform announces that the first patient has been recruited in a study evaluating CERAMENT® G and CERAMENT® V in patients undergoing hip and knee arthroplasty revisions. Professor Carlo Romanò is the Principal Investigator for the study, which will take place at 6 different clinical centers in Italy and is expected to recruit approximately 135 patients.

The investigator-led study is an open-label, prospective cohort, observational clinical trial designed to evaluate the effectiveness and safety of CERAMENT G or CERAMENT V when used to fill bone defects in the tibia and/or femur shaft and/or acetabulum in patients scheduled for two-stage hip or knee prosthesis re-implantation for periprosthetic joint infections (PJIs).

The results from the study will be compared to a cohort of patients, at the same clinical centers, who were treated using current standard, of care.

The aim of the study is to show an improved clinical outcome and a lower infection rate for the CERAMENT G or CERAMENT V group compared to the retrospective control cohort where neither CERAMENT G or CERAMENT V were used.

One endpoint of the study will be the rate of PJIs according to the Musculoskeletal Infection Society (MSIS) criteria during the one year follow-up.

Professor Carlo Romanò, the study’s Principal Investigator, said: "PJIs remain one of the most feared complications after orthopedic surgery. The ability of microorganisms to adhere to the surface of an implant and to immediately produce a protective biofilm is currently considered as the main challenge in the treatment of implant-related infections. At present, there is no accepted approach for preventing recurring PJIs in patients undergoing revision arthroplasty. We have already conducted a pilot study that showed a beneficial outcome from using CERAMENT G and CERAMENT V in a small series of patients undergoing two-stage knee and hip arthroplasty revisions. The aim of the larger study which we are now conducting is to confirm these promising initial results in a larger cohort of patients and compare the results to a retrospective control.”

Richard Davies, CEO of BONESUPPORT, commented: “The start of this study is a key step in our strategy to build a compelling data set to support the prophylactic use of both CERAMENT G and CERAMENT V in patients undergoing hip and knee arthroplasty revisions. We are confident that CERAMENT G and CERAMENT V’s ability to elute the antibiotics gentamicin and vancomycin respectively, while at the same time, remodeling to bone, will allow them to deliver a reduction in the rate of PJIs in this study.”
About BONESUPPORT™

BONESUPPORT is an innovative and rapidly growing commercial stage orthobiologics company, based in Lund, Sweden. The Company develops and commercializes innovative injectable bio-ceramic bone graft substitutes that remodel to the patient’s own bone and have the capability of eluting drugs directly into the bone void. BONESUPPORT’s marketed bio-ceramic bone graft substitutes CERAMENT® BONE VOID FILLER (BVF), CERAMENT® G and CERAMENT® V are all based on the Company’s novel and proprietary CERAMENT technology platform.

The Company’s products are targeting a large addressable market opportunity across trauma, chronic osteomyelitis (bone infection), revision arthroplasty (replacement of a joint prosthesis) and infected diabetic foot.

BONESUPPORT’s total sales increased from SEK 41 million in 2014 to SEK 105 million in 2016, representing a compound annual growth rate of 60 percent. The Company’s financial target is to achieve revenue exceeding SEK 500 million in the financial year 2020, with a gross margin exceeding 85 percent and a positive operating profit.

The Company’s research and development is focused on the continuing development and refinement of its CERAMENT technology to extend its use into additional indications by the elution of other drugs and therapeutic agents. The Company currently has a pipeline of pre-clinical product candidates that have been designed to promote bone growth.

BONESUPPORT is listed on Nasdaq Stockholm and trades under the ticker “BONEX” (ISIN code: SE0009858152). Further information is available at www.bonesupport.com

*CERAMENT G: Not available in the United States, for investigational use only. CERAMENT V: Not available in the United States.

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