PRESS RELEASE

BONESUPPORT™ Announces Nature Publication of Pre-Clinical Study Highlighting CERAMENT™’s Attractive Bone Remodeling Properties and as a Local Drug Delivery Platform for Bone Disease

Lund, Sweden, 1 June, 2016 – BONESUPPORT AB, an emerging leader in innovative injectable bioresorbable bone graft substitute products to treat bone voids caused by trauma, infection, disease or related surgery today announced the publication of a paper in Nature Scientific Reports: A Biphasic Calcium Sulphate Hydroxyapatite Carrier Containing Bone Morphogenic Protein-2 and Zoledronic Acid Generates Bone (Raina, D et al., reference below). The paper covers a pre-clinical study which demonstrated that CERAMENT™ loaded with a combination of recombinant human bone morphogenic protein 2 (“rhBMP-2”) plus zoledronic acid (“ZA”) in very low doses was able to quantitatively and qualitatively generate a higher amount of mineralized bone volume. The study also showed in vivo that the mineralized volume was significantly higher when CERAMENT™ was combined with rhBMP-2 and ZA (21.4±5.5mm³) as compared to CERAMENT™ in combination with just rhBMP-2 (10.9±2.1mm³). Raina, D. et al.

The findings highlight the attractive properties of CERAMENT™ as an injectable carrier material that can mimic natural bone matrix. CERAMENT™ benefits from several advantages such as a high degree of protein encapsulation, sustained release behavior and improved surgical handling. The biocompatibility and bioresorbability of the biphasic microporous material which sets in situ make it suitable as a carrier with a controlled release of encapsulated or chemically bound additives.’ Raina, D. et al.

Authors of the publication stated, “There is a clear need for bone substitutes that can safely and effectively replace autograft via a combination of bone growth and remodeling. There is increasing demand and the absence of a viable solution for replacing large volumes of bone that clearly requires new innovative bone graft solutions. The results that we have published shows that it could be possible to develop a single stage method based on the unique properties of CERAMENT™|BONE VOID FILLER (BVF) to deliver a combination of the rhBMP-2 and ZA locally at the site where significant new bone formation is needed”. Raina, D. et al.

The authors note that previously BMPs have not been proven to induce better bone healing than autograft suggesting that there is a clear need for an improved delivery platform, and that the limitations of delivery methods used to-date have led to varying clinical outcomes. These include carboxymethyl cellulose, bovine particle carriers and collagen sponges, which additionally can cause local inflammatory reaction. The study findings suggest that using CERAMENT™ as a platform to co-deliver a combination of rhBMP-2 and ZA with a synergistic effect can potentially improve the standard of care for patients afflicted with bone disease. Raina, D. et al.

Richard Davies, CEO of BONESUPPORT commenting on today’s announcement said, “The pre-clinical results in this prestigious publication highlight an unmet medical need for a single-stage delivery platform with properties that not only foster bone healing, but also enable local delivery of a range of therapeutics. It discusses the advantageous properties of CERAMENT™ as a drug eluting material which we have been demonstrating in clinical practice with antibiotic containing CERAMENT™ G & V. We have received favourable physician feedback about the efficacy of these products in the
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management of patients with osteomyelitis. We are encouraged about the potential of our platform to develop further products to treat specific groups of patients with bone disease. “

Reference


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Notes to Editor

About BONESUPPORT™

BONESUPPORT AB has developed CERAMENT™ as an innovative range of radiopaque injectable osteoconductive bioceramic products that have a proven ability to heal defects by remodeling to host bone in six to twelve months. Our products are effective in treating patients with fractures and bone voids caused by trauma, infection, disease or related surgery. Our lead product, CERAMENT™ | BONE VOID FILLER (BVF) addresses important issues facing health care providers, such as avoiding hospital readmissions and revision surgery that result from failed bone healing and infection caused by residual bone voids. CERAMENT™ | BVF is commercially available in the U.S., EU, S.E. Asia and the Middle East.

CERAMENT™’s distinctive properties as a drug eluting material have been validated in clinical practice by CERAMENT™ | G and CERAMENT™ | V, the first CE-marked injectable antibiotic eluting bone graft substitutes. These products provide local sustained delivery of gentamicin and vancomycin, respectively. The local delivery feature enables an initial high concentration of antibiotics to the bone defect and then a longer sustainable dose above the minimal inhibitory concentration (MIC) to protect bone healing and promote bone remodeling.

CERAMENT™ | G and CERAMENT™ | V have demonstrated good results in patients with problematic bone infections including osteomyelitis. They are also used prophylactically in patients who are at risk for developing infection. CERAMENT™ | G and CERAMENT™ | V are available in the EU.

BONESUPPORT AB was founded in 1999 by Prof. Lars Lidgren, an internationally respected scientist who has been the President of various musculoskeletal societies. BONESUPPORT’s mission is to bring people with bone and joint diseases back to an active life. The company is based in Lund, Sweden.

BONESUPPORT™ is a registered trademark.

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