

BONESUPPORT™ FILES FDA SUBMISSION FOR CERAMENT® V

BONESUPPORT™, a leading company in orthobiologics for the management of bone injuries, today announces that the company has submitted market authorization application for its antibiotic eluting bone graft substitute, CERAMENT® V (vancomycin), with the Food and Drug Administration (FDA), for the indication bone infection.

The market approval for CERAMENT® G in 2022 was based on extensive efficacy and patient safety data, with nearly 17,000 clinical data points. The clinical data, from several published studies, demonstrated that CERAMENT G is superior to previous standard options in managing bone infections. With market authorization for CERAMENT V, physicians would be equipped with an additional tool to manage bone infections, primarily caused by Methicillin-Resistant Staphylococcus eg. MRSA or MRSE. CERAMENT V in Europe, where the product has had market approval for several years, represents 15% of the sales of antibiotic-releasing products.

Bone grafts with local antibiotic release have proven to be a very important tool in the ambition to drastically reduce the need for systemic antibiotic use* and combat antibiotic resistance.

CERAMENT V has previously received the categorization of "breakthrough device" for the indication of bone infection from the FDA.

*Dudareva M, Kumin M, Vach W, Kaier K, Ferguson J, McNally M, Scarborough M. Short or Long Antibiotic Regimes in Orthopaedics (SOLARIO): a randomized controlled open-label non-inferiority trial of duration of systemic antibiotics in adults with orthopaedic infection treated operatively with local antibiotic therapy. *Trials* 2019; 20: 693

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About BONESUPPORT™

BONESUPPORT (Nasdaq Stockholm: BONEX) 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. BONESUPPORT's bone graft substitutes are based on the patented technology platform **CERAMENT**. The company is conducting several clinical studies to further demonstrate the clinical and health economic benefits its products deliver. The company is based in Lund, Sweden, and the net sales amounted to SEK 899 million in 2024. Please visit www.bonesupport.com for more information.

BONESUPPORT and CERAMENT are **registered trademarks** of BONESUPPORT AB.

Attachments

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