Press Release
01 July 2024 14:30:00 CEST

The market submission for CERAMENT® V in the US will be a 510(k)

BONESUPPORT™, a leading company in orthobiologics for the management of bone injuries, today announces that the company's submission for marketing authorization for its antibiotic eluting bone graft substitute, CERAMENT V (vancomycin), following discussions with the U.S. Food and Drug Administration (FDA), will proceed through a 510(k) pathway, instead of a De Novo application.

The marketing approval for CERAMENT® G in 2022 was based on extensive efficacy and patient safety data, with nearly 17,000 clinical data points. Since CERAMENT V shares the same mechanism of action as CERAMENT G, despite containing a different antibiotic, CERAMENT G can serve as a predicate device for CERAMENT V. The submission is still scheduled for the first quarter of 2025.

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

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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 591 million in 2023. Please visit **www.bonesupport.com** for more information.

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Attachments

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