Press Release

Accelerated road to market approval for CERAMENT® G in the US – BONESUPPORT™ submits De Novo application

Lund, Sweden, 8 am CET, 23 March 2020 – **BONESUPPORT™**, an emerging leader in orthobiologics for the management of bone injuries, today announced that the company will submit a De Novo application to the US Food and Drug Administration (FDA) to obtain a market approval for the company's antibiotic-releasing product CERAMENT G. The application is specified for the indication osteomyelitis (bone infection) and can potentially result in an approval at the latter end of 2020.

During the winter, BONESUPPORT has been in dialogue with the US Food and Drug Administration, the FDA, to investigate whether CERAMENT G could, through a De Novo application, obtain market approval for the indication osteomyelitis. A De Novo application can be made when there is no comparable established alternative ("predicate device") on the market.

The dialogue with the FDA has resulted in CERAMENT G being granted designation as a "Breakthrough Device" and that BONESUPPORT has decided to submit a De Novo application in April 2020.

"Breakthrough device" categorization can be assigned to products that are considered to provide more effective treatment of severe conditions. The purpose is to provide an expedited review of the application for market approval.

"The benefits of CERAMENT G for patients and clinics are validated in a number of very strong clinical studies that have paved the way for our strong sales in Europe, where CERAMENT G accounts for a clear majority of our sales. It shows the potential of our antibiotic-releasing products as we now work for accelerated market approval in the United States. A positive message on the De Novo application would shorten the route for CERAMENT G to the US market by about 18 months," said Emil Billbäck, CEO of BONESUPPORT.

Following BONESUPPORT's application submission for market approval, is a period where the FDA is reviewing the extensive documentation. If everything goes according to plan, BONESUPPORT expects a market approval to be obtained at the latter end of 2020. However, the length of the actual review is difficult to predict since the process is dependent on FDA's feedback and potential requests for further information or documentation.

CERAMENT G enables local antibiotic release, which significantly reduces the risk of reinfection and amputation in bone infection, as well as reduces the risk of developing antibiotic resistance, which means we see a huge potential in the US market.

Osteomyelitis is a severe condition where the infection damages and prevents the natural bone healing process and is estimated to account for about 50 percent of all non-trauma-related amputations. Each year, approximately 50,000 patients with osteomyelitis are treated with bone graft. The market for these treatments is estimated at about $ 100 million.

BONESUPPORT has previously announced that the company plans to submit a premarket approval application (PMA) for CERAMENT G to the FDA in 2021. The De Novo application

applies to the indication osteomyelitis (bone infection) and BONESUPPORT still intends to submit a PMA application for further indications, including trauma, by the end of 2021.

Due to the above press release, BONESUPPORT will hold a conference call / webcast: Monday, March 23, at 9:30 am.

To follow the webcast:
https://tv.streamfabriken.com/2020-03-23-bonesupport-pressconference

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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 that its products deliver and a Premarket approval filing with the FDA (USA) for CERAMENT G is planned in 2021. The company is based in Lund, Sweden, and the net sales amounted to SEK 155 million in 2019. Please visit www.bonesupport.com for more information.