Press Release

BONESUPPORT's FDA notification: Approval on DeNovo pathway for CERAMENT G will require additional data and clarifications

Lund, Sweden, 14:30 CET, 27 02 21 –BONESUPPORT ™, a leading company active in orthobiology for the treatment of skeletal injuries, today announced that the company has received a notification from the US Food and Drug Administration (FDA) that the company's DeNovo application for CERAMENT G for bone infections can not be concluded without additional data and clarifications.

"We had obviously hoped to launch CERAMENT G in the US, for the indication bone infections, during the spring 2021, but the approval process with CERAMENT G being "the first of its kind", will require additional interactions with FDA," said Emil Billbäck, CEO of BONESUPPORT.

In March 2020, the product was classified as a "breakthrough device" by the FDA. A DeNovo application for CERAMENT G for bone infections was submitted in April 2020. The DeNovo pathway is used when there is no comparable established device ("predicate device") on the market.

"We will work to accommodate the requests by the FDA. Good guidance on requirements to reach approval has been given by the FDA and the dialogue is very productive" said Emil Billbäck.

Revised timing for potential DeNovo approval for the indication bone infections is estimated for Q1 2022.

As previously announced, BONESUPPORT intends to start the registration process regarding CERAMENT G for non-infected indications, including trauma, during the end of 2021, through a PMA pathway based on the outcome of the FORTIFY study. This process is independent from DeNovo.

BONESUPPORT will hold a conference call and an online presentation on March 1st at 09.30 am CET. The call will be hosted by Emil Billbäck, CEO and Håkan Johansson, CFO who will present and answer questions. The presentation will be held in English.

Weblink

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EU Market Abuse Regulation
This information is such information as BONESUPPORT HOLDING AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 14:30 CET on 27 02 21

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 181 million in 2020. Please visit www.bonesupport.com for more information.