

Press Release  
Kista, October 13th, 2021

## Chordate Medical Holding AB (Publ.) launches pre-study for FDA market approval in the United States

**Chordate Medical has made a strategic decision to initiate a pre-study to apply for marketing authorization for the K.O.S treatment for chronic migraine with the US Food and Drug Administration, FDA. The work is carried out in collaboration with a reputable American consulting company. The pre-study will begin immediately and can be expected to be completed within the first quarter of 2022, when a decision on the choice of strategy can be made.**

Chordate's initial analysis indicates that this is a so-called DeNovo application, and the company has focused the project on tentatively moving forward to the submission of a complete application during the second half of 2022.

“As a natural step after the CE mark came into place in May earlier this year, we now want to move forward with market permits in the US as well. This is a longer project, but an important step to take in the strategy of building company value. This ambition to procure a US market permit does not mean that we have changed the model on how we build our proof of market. However, our assessment is that an approved DeNovo application in the long run gives us a broader set of options and makes Chordate more interesting for the medtech industry in general”, says Anders Weilandt, CEO of Chordate.

“The project is to first carry out a pre-study to select the appropriate strategy, then a pre-submission step to understand the perspective of the FDA on a tentative submission, and finally the formal application. An important issue is to find out what level of scientific evidence the FDA wants to see in an application for acceptance. This will take time and need a clear focus on our part.”

### Information:

This disclosure contains information that Chordate Medical Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the contact person below, on October 13th, 2021, at 10:00 a.m. CET.

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### About Chordate

Chordate Medical Holding AB (publ) is a medical technology company that for over ten years has developed, patented and CE-marked a new neuromodulation treatment technology for chronic nasal congestion (rhinitis) and chronic migraine. The company offers its product via distributors to clinics and hospitals in selected European markets, Israel and Saudi Arabia. Chordate Medical's share is listed on the Nordic Growth Market NGM - SME (ticker: CMH). Read more at <https://www.chordate.com/en/>