

Press release
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Chordate Medical completes first phase in the US: moves forward with De Novo application

Chordate Medical Holding (publ) has together with regulatory quality consulting firm RQM + completed the pre-study to apply for a marketing authorization for the K.O.S treatment for chronic migraine at the US Food and Drug Administration, FDA. Based on the results, Chordate chooses to initiate a so-called De Novo application. The next phase has begun and includes a pre-submission meeting with the FDA to get the agency's preliminary view on how the final application should be designed.

“The pre-study shows that the most advantageous strategy for Chordate and our treatment is a De Novo application, which involves an application process that is adapted to medical devices with low or medium risk without already launched equivalents in the US market”, says Anders Weilandt, CEO of Chordate Medical.

Chordate announced in October 2021 that the company had made a strategic decision to initiate a pre-study to apply for a marketing authorization for the K.O.S treatment for chronic migraine at the FDA. Following the completion of the pre-study, Chordate will now carry out a pre-submission step to understand the perspective of the FDA on a tentative submission, after which the complete De Novo application will be submitted.

“It is satisfying that we are done with the first phase and following the schedule. A market condition in the USA is an important step in our strategy to build company value and it will give the company greater choice for future strategic decisions”, says Anders Weilandt.

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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 Nasdaq First North Growth Market Stockholm (ticker: CMH). Read more at www.chordate.com/en/

Chordate's Certified Adviser on Nasdaq First North Growth Market Stockholm is Västra Hamnen Corporate Finance AB, +46 40 200 250, ca@vhcorp.se.

N.B. The English text is an in-house translation of the original Swedish text. Should there be any disparities between the Swedish and the English text, the Swedish text shall prevail.