

Press release

Chordate successfully completes Interim Analysis for ongoing multicenter clinical study of intranasal kinetic oscillation stimulation for preventive treatment of chronic migraine

Interim results

Kista, Sweden, May 7, 2019 — Chordate Medical Holding AB's (publ) ("Chordate"), a specialty medtech company that focuses on developing neuromodulating systems for treating chronic migraine and non-allergic rhinitis, today announced the results of the interim analysis of the ongoing clinical study on migraine with an investigative product - Kinetic Oscillation Stimulation System S211 (K.O.S-treatment). As part of the interim analysis, which was press released the 22nd of February, an independent data monitoring committee (DMC) conducted a statistical probability analysis focused on efficacy factors for the first 50 patients enrolled. Based on the results, the committee recommends continuation of the study, without a need for changing the number of patients for the final analysis.

"It is with great satisfaction I can conclude that the recommendation we have received confirms that the study is on track, as originally designed. The fact that the DMC recommend continuation with the same population size is a particularly strong message, which we interpret as a sign of probable efficacy. However, due to the limited number of subjects in the analysis this interim result is without statistical significance, thus far. The reader is therefore cautioned that this is an ongoing clinical study, and that its final result can only be judged once the study is completed and reported.

However, based on this confirmation we will now continue to prepare the registration process for a CE-mark of the migraine indication. We will also start to plan the market introduction for this treatment, that we believe can develop into a great non-pharmaceutical alternative for many chronic migraine patients in the world", says Anders Weilandt, CEO of Chordate.

The randomized, placebo-controlled, double-blind, multicenter study is being conducted at four neurology clinics in Germany. The study intends to enroll up to 140 subjects and is designed to evaluate the efficacy and safety of the K.O.S-treatment, with the primary endpoint to detect mean change from baseline (4-week screening period) in monthly headache days with moderate to severe intensity, in a 4-week performance assessment period. The fifty percent of the patients in the K.O.S arm are receiving active treatment from the S211, while the other half of the patients are receiving a validated sham/placebo treatment from the same equipment. The study enrolls patients with diagnosed chronic migraine (≥ 15 days/month of headache, whereof > 8 days with migraine) and is planned to be completed during the late fall of 2019.

The Migraine Market

According to scientific literature, migraine, the seventh disabler, has a lifetime prevalence of around 15% of the population, of which around 1.4-2.2% suffer from chronic migraine. It can significantly limit the daily activities of sufferers as well as having considerable psychological and economic impacts, with accumulated costs amounting to 100 billion Euro in the European countries. Although chronic migraine is associated with substantial disability and

costs, few treatments have been shown to be effective. The global migraine drugs market size has a forecasted value of USD 7.7 billion in 2025 after showing a CAGR of approximately 18%. However, treatments with medicine is not all straight forward, many of the available products today comes with strong side effects, which for some patients are intolerable.

During the past couple of years, other more non-traditional ways to try and treat migraine, for example onabotulinumtoxinA (treatment with Botox), has been shown to reduce the frequency of headaches in patients with chronic migraine. Its benefits and potential use in migraine were observed incidentally while treating patients cosmetically for wrinkles. However, this type of treatment involves certain steps that many patients may find discomfoting. For example, a single treatment could involve around thirty injections around the head area, alongside with multiple follow-up treatments.

At the same time, this shows that patients are willing to try new types of methods for treating migraine besides conventional medication. Chordate, with their Kinetic Oscillation Stimulation treatment, could play an important role and contribute with a new non-pharmaceutical alternative for chronic migraine patients.

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Information:

This information is information that Chordate Medical Holding AB (publ) is required to disclose under the EU Market Abuse Regulation. The information was provided, through the contact person above for publication on May 7, 2019 at. 08:30 CET.

TO THE EDITORS

About Chordate

Chordate Medical Holding AB (publ) is a medical technology company that during ten years has developed, patented and CE-marked a new treatment method for chronic migraine and non-allergic rhinitis through neuromodulation. The company sells its product system including treatments through its own sales organization as well as distributors to clinics and hospitals, which in their turn treat patients. Read more at www.chordate.com. Mangold Fondkommission AB, tel. +46 8 5030 1550, is the company's mentor and liquidity guarantee at NGM Nordic MTF.