Nexstim Plc reports results of the supplementary Phase III E-FIT trial

Company announcement, Helsinki, 3 September 2018 at 9:00 AM

Nexstim Plc (NXTMH:HEX, NXTMS:STO) ("Nexstim" or the "Company"), the targeted neuromodulation company developing and marketing pioneering navigated non-invasive brain stimulation systems for both therapeutic and diagnostic application, announces it has completed its supplementary Phase III clinical trial, known as E-FIT (ELECTRIC FIELD NAVIGATED 1HZ RTMS FOR POST-STROKE MOTOR RECOVERY TRIAL), evaluating the use of Nexstim's NBT® system in upper extremity motor rehabilitation following stroke.

The supplemental E-FIT trial was conducted at five leading clinical centres in the US and recruited a planned total of 60 patients. The E-FIT trial used a new sham comparator that was designed to provide data to supplement the completed Phase III NICHE trial, which demonstrated excellent results in the active group, with 2/3 patients showing a clinically meaningful response.

In the primary efficacy analysis, the E-FIT trial dataset was combined with data from the active trial arm of the previously completed Phase III NICHE trial as recommended by the FDA. In the combined dataset no statistically significant difference in percentage of patients obtaining a clinically important improvement of hand and arm function between active and sham trial arms were observed. Similarly, in a secondary analysis of the E-FIT dataset alone, no statistically significant differences between the trial arms were observed (60% vs 50%, active and sham NBT, respectively, p=0.62). The results in both trial arms exceeded the literature based response expectation of approximately 1/3 in occupational therapy alone.

Martin Jamieson, Chairman and CEO, Nexstim Plc commented: "We are obviously disappointed with the E-FIT trial results, even though both trial arms demonstrated clinically superior outcomes. Using the approach of inhibiting the healthy hemisphere of the brain following a stroke, we were unable to demonstrate the clear cut benefit anticipated. As a result, we have decided to focus therapeutic applications on depression and further evaluate chronic neuropathic pain, where stimulation of specific areas of the brain have proved effective. The Nexstim SmartFocus™ TMS system is particularly appropriate for targeted stimulation due to its highly accurate, repeatable dosing. We received our FDA 510k approval for MDD (Major Depressive Disorder) in November 2017 and early sales have proved very promising. MDD represents a significant commercial opportunity with an estimated addressable market of about 6 million patients in the US and Europe in total, representing a treatment value of over EUR 40 billion. We look forward to continuing build our sales base in Pre-surgical mapping and MDD in the US and other geographic centres."

NEXSTIM PLC
Martin Jamieson, Chairman and CEO

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About Nexstim Plc

Nexstim is a targeted neuromodulation company focused on developing and commercializing its world-leading navigated non-invasive brain stimulation technology, known as SmartFocus™ TMS (transcranial magnetic stimulation), for therapeutic applications, namely depression and chronic pain via its Navigated Brain Therapy (NBT®) system.

Nexstim has launched its NBT® system in the US for the treatment of Major Depressive Disorder (MDD) following clearance from the FDA for marketing and commercial distribution for this indication. The NBT® system is CE marked in Europe for the treatment of stroke, major depression and chronic neuropathic pain.

In addition, Nexstim is commercialising its Navigated Brain Stimulation (NBS) system for diagnostic applications, based on the same technology. The NBS system is the only FDA cleared and CE marked navigated TMS system for pre-surgical mapping of the speech and motor cortices of the brain.

Nexstim shares are listed on the Nasdaq First North Finland and Nasdaq First North Sweden. For more information please visit www.nexstim.com.