Data Safety Monitoring Board Recommends Continuation of Nexstim Plc's Phase III Stroke Therapy Trial

Helsinki, 26 September 2015 at 12:00 noon

- *Interim data analysis by an independent Data Safety Monitoring Board shows that safety criteria are met and trial should continue without any modifications*

Nexstim Plc (NXTMH:HEX, NXTMS:STO), a medical technology company aiming to improve rehabilitation for stroke patients through the use of non-invasive brain stimulation, announces today that it has received a recommendation from the Data Safety Monitoring Board (DSMB), an independent committee of experts monitoring the trial, to continue the Phase III stroke therapy NICHE trial, without any modifications. The first interim analysis on the NICHE (Navigated Inhibitory rTMS to Contralesional Hemisphere) trial using Nexstim's Navigated Brain Therapy (NBT®) was performed after 81 patients reached their primary safety outcome assessment, on track, at six months post-treatment. As previously announced, the second interim analysis is expected to occur in Q1 2016 and the study is scheduled to complete in Q3 2016 when full data will be disclosed.

Nexstim commenced the pivotal, randomised, sham-controlled, double-blinded multi-centre Phase III study in H1 2014 to demonstrate the effects of its NBT® system on upper limb motor rehabilitation post-stroke. The two year study is being conducted on up to 198 patients at 12 prominent rehabilitation sites in the USA. The primary objective of the study is to demonstrate a difference between the active NBT® and sham groups of patients to achieve a clinically important functional improvement from baseline to six months post treatment. The safety data was assessed on all patients 160 recruited to-date.

This announcement has no impact on Nexstim's financial outlook for FY 2015. Nexstim will review the future potential financial impact on the company as part of the planning of its commercialisation strategy.

Commenting on the DSMB's recommendation to continue the trial, Janne Huhtala, Chief Executive Officer of Nexstim, said: *"The DSMB recommendation confirms the good safety profile of our product and de-risks the programme heading into the pivotal outcome data. With positive outcome data, Nexstim will be in a strong position to take a significant market position with NBT® for stroke therapy. We continue the unmodified trial, as planned, with excitement and with the aim of bringing this important product to patients and care givers in rehabilitation centres as quickly as possible."*

Commenting on the trial results to date, Dr Richard L. Harvey, Medical Director, Center for Stroke Rehabilitation, Rehabilitation Institute of Chicago (RIC), said: *"We are encouraged by the data generated so far from this groundbreaking study which offers hope to stroke patients as a new and effective therapy. NBT® offers promise as an important new therapy for stroke survivors globally and could be a real breakthrough for the major debilitating condition that has until now been limited by a lack of any real medical advancement."*

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About Nexstim Plc

Nexstim is a medical technology company aiming to improve rehabilitation for stroke patients. Nexstim has pioneered its technology in brain diagnostics with the Navigated Brain Stimulation (NBS) system as the first and only FDA-cleared and CE-marked navigated Transcranial Magnetic Stimulation (nTMS) device for pre-surgical mapping of the motor and speech cortices. Based on the same technology platform, the company has developed a device for stroke therapy called Navigated Brain Therapy (NBT®). In H1 2014, Nexstim initiated a two-year pivotal Phase III study at 12 sites in the US aiming to demonstrate the effectiveness of NBT® and gain FDA clearance for commercialisation in post-acute stroke therapy in the US. Nexstim's shares are listed on Nasdaq First North Finland and Nasdaq First North Sweden. For more information please visit www.nexstim.com.

About NBT®

Navigated Brain Therapy (NBT®) is a non-invasive system that uses navigation to accurately target therapy directly to the cortical structures believed to be involved in brain dysfunctions. The device is CE-marked to offer patients a personalised treatment for major depression. In addition, the system is CE-marked for use in patients recovering from stroke as a supplement to conventional rehabilitation.

About NICHE (Navigated Inhibitory rTMS to Contralesional Hemisphere)

The NICHE trial is a pivotal, prospective, multi-centre, randomised, controlled, double-blinded study combining active Nexstim NBS-guided 1Hz rTMS or sham-rTMS targeting the healthy hemisphere with standardised task-oriented rehabilitation will be conducted in patients with post-stroke motor impairment. The therapy will be provided for six weeks and primary outcome assessed six months later. For more information on the trial, please visit:
https://clinicaltrials.gov/ct2/show/NCT02089464