Nexstim Plc Receives Interim Analysis Information and Recommendation from DSMB for Phase III Stroke Therapy Trial

Helsinki, 28 February 2016 at 1:00 pm

- Pre-specified stopping criteria for futility have been met and the trial will not meet its primary endpoint
- Nexstim will analyse the DSMB recommendation further before deciding upon the continuation of the Phase III trial
- DSMB recommends that the study team and subjects remain blinded and data collection be completed

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 the Data Safety Monitoring Board (DSMB), an independent committee of experts monitoring the Phase III stroke therapy NICHE trial, has reviewed the interim analysis data. The DSMB notes that the pre-specified stopping criteria for futility have been met and therefore the trial will not meet its primary endpoint. However the DSMB further notes that they acknowledge that the treatments and enrolment have been completed. They recommend that the study team and subjects remain blinded and data collection be completed.

The second interim analysis on the NICHE (Navigated Inhibitory rTMS to Contralesional Hemisphere) trial using Nexstim's Navigated Brain Therapy (NBT®) was performed for 138 patients as well as safety data was reviewed for all 199 patients recruited to-date. No safety concerns were observed.

Nexstim will analyse the DSMB recommendation further before deciding upon the continuation of the Phase III trial. With treatment on all patients now complete the next phase of the trial would be to receive results from the third and final cohort's six month follow-up assessment.

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 199 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.

This announcement has potential implications for Nexstim's long term strategy. Nexstim will now conduct a review of the future strategy for NBT® as part of the company's wider strategy and an update announcement will be made in due course. More information of Nexstim's future outlook for FY 2016 will be given as part of the financial statement release on Monday February 29th, 2016. Nexstim's management will discuss the milestone results during the scheduled analyst, media and investor conference call on Monday 29 February 2016, the details of which were announced on Thursday 11 February 2016.

NEXSTIM PLC
Janne Huhtala, CEO

For further information please visit www.nexstim.com or contact:

Nexstim +358 (0)40 8615046
Janne Huhtala, Chief Executive Officer janne.huhtala@nexstim.com

UB Securities Ltd (Certified Adviser) +358 (0)9 2538 0246

Consilium Strategic Communications +44 (0)20 3709 5700
Mary-Jane Elliott / Ivar Milligan / Laura Thornton nexstim@consilium-comms.com

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