Nexstim Plc provides key update on Phase III NICHE stroke therapy trial

Company announcement, Helsinki, 31 March 2016 at 9:00 am

- *NICHE interim data analysis shows significant clinically meaningful responses and improvement in both trial groups (active NBT® and surprisingly also in sham group) without any safety concerns*
- *No separation between groups caused the DSMB futility analysis to meet its futility criteria at the second milestone of 138 patients*
- *Nexstim to stop the trial and to submit the FDA 510(k) De Novo*

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 an update to the regulatory release issued on 28 February 2016. The release noted the Data Safety Monitoring Board's (DSMB) recommendation based on the interim results from the first two tranches of the NICHE (Navigated Inhibitory rTMS to Contralesional Hemisphere) study triggering futility analysis criteria. Further analysis has shown clinically meaningful responses and surprisingly, improvement in both the active NBT® and sham trial groups.

Importantly, the NBT® active treatment in the NICHE trial gained highly clinically meaningful positive results, with over 2/3 of the patients responding. Surprisingly, the sham treatment also resulted in similar clinical responses, well above expected sham response levels, albeit from a different stimulation method to the active NBT® treatment. Both stimulation protocols were provided with Nexstim proprietary e-field based navigation technology. The unexpected sham treatment data have led Nexstim to file a patent application on this novel stimulation method. The response in the sham group caused the interim analysis of the study to trigger the futility analysis criteria because of the lack of separation of the groups. The primary endpoint of the study was 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. No safety concerns were observed throughout the study.

Treatments within the NICHE trial were completed at 12 prominent rehabilitation sites in the USA in all 199 patients, as planned, and the remaining patients are in a 6 months follow up period. Nexstim will now stop and unblind the NICHE trial to analyse the data collected so far.

Nexstim will submit the FDA 510(k) De Novo based on the clinical data in the second quarter 2016 and work towards finding a path forward for this significant therapeutic treatment to increase the benefits of this clinical patient work compared to current clinical rehabilitation. The NBT® is already CE-marked for stroke rehabilitation.

Commenting on the announcement, Janne Huhtala, CEO of Nexstim, said: "Whilst the DSMB's recommendation in late February was a disappointing result for Nexstim, we have been positively surprised that both groups were responding in a clinically meaningful way bringing strong clinical benefit to stroke patients. The outcome showed that more than two thirds of patients responded in both groups at a higher level than the expected normal occupational therapy response. We are now analysing the data and look forward, with significantly restored optimism, to updating the market in due course."

Commenting on the announcement, Dr. Richard Harvey, Medical Director, Center for Stroke Rehabilitation, Rehabilitation Institute of Chicago (RIC), said:
"The overall level of functional improvement in NICHE is high for this post-acute stroke patient population. This degree of therapeutic response is a very positive step forward for arm and hand recovery in patients with stroke. Further exploration of this technology to enhance the current rehabilitation outcomes to this extent is a next step to pursue."

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Janne Huhtala, CEO

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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®). 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, sham-controlled, double-blinded Phase III 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. Nexstim commenced the study in H1 2014 to demonstrate the effects of its NBT® system on upper limb motor rehabilitation post-stroke. 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