Nexstim Plc submits FDA 510(k) De Novo documentation for NBT®

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Nexstim Plc (NXTMH:HEX, NXTMS:STO), a medical technology company with a pioneering navigated non-invasive brain stimulation system, announces the submission of FDA 510(k) De Novo documentation for its Navigated Brain Therapy (NBT®) system for stroke rehabilitation as a next step towards securing marketing clearance in the United States.

Further to the Company's announcement on 31 March 2016, the documentation submitted to the FDA on the NICHE (Navigated Inhibitory rTMS to Contralesional Hemisphere) study supports the hypothesis of a new mode of therapy. The submission includes full data from a total of 173 patients.

The trial analysis showed clinically meaningful responses and, surprisingly, significant improvement in both the active NBT® and sham trial groups. Upon detailed analysis of the data, the results of the study showed that 66 percent of subjects responded to treatment by gaining clinically important improvement of function. There was no statistically significant difference between the active and sham treatment arms. Patients in both study arms obtained greater functional benefits than those expected by experts and in published research. The submission includes the Company's analysis of these findings which concludes that the control group was active, explaining the unexpected positive results.

Nexstim expects to have initial feedback from FDA within 60 to 90 days. The NBT® system is already CE-marked for stroke rehabilitation. The unexpected sham treatment data has also led Nexstim to file a patent application on this novel stimulation method.

Commenting on the submission, Martin Jamieson, Chairman and CEO of Nexstim, said: "This submission, and the research behind it, demonstrates the validity of these data. We're pleased to be developing this additional treatment method and look forward to the FDA's response. The therapeutic benefit of our NBT® has the potential to bring a very real improvement to rehabilitation for those recovering from a stroke compared to current clinical practice."

Commenting on the recent study, 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. Such a therapeutic response would be very helpful for recovering patients. Finding a way to enhance the current rehabilitation outcomes to this extent is a next step to pursue."

NEXSTIM PLC
Martin Jamieson, Chairman and CEO

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About Nexstim Plc

Nexstim is a medical technology company which 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) system for pre-surgical mapping of the motor and speech cortices. Based on the same technology platform, the company has developed a system called Navigated Brain Therapy (NBT®) which is CE-marked for major depression and stroke therapy. Nexstim's shares are listed on Nasdaq First North Finland and Nasdaq First North Sweden. For more information please visit www.nexstim.com