Nexstim Plc agrees the next steps of the NBT stroke de novo submission with the FDA

Company announcement, Helsinki, 15 September 2016 at 9 am

Nexstim Plc (NXTMH:HEX, NXTMS:STO), a medical technology company with a pioneering navigated non-invasive brain stimulation system, announces that Nexstim has, on September 14, 2016, discussed the pivotal stroke multicenter trial (NICHE, Navigated Inhibitory rTMS to Contralesional Hemisphere) safety and efficacy results with the US Food and Drug Administration (FDA) and in good collaboration with the FDA agreed the next steps for the de novo submission.

Based on the discussions, Nexstim concludes that the FDA has no concerns about the safety of the NBT device. In the same discussion, Nexstim has agreed with the FDA that a limited size trial using a sham comparator of a different design to that used in the NICHE trial will be designed and approved according to the guidance received from the FDA. To support the smaller study size Nexstim has agreed to provide comparisons of the efficacy of upper extremity motor rehabilitation between published studies, expert opinions and NICHE trial results. Nexstim estimates that the design of a limited size trial with a new sham comparator will be approved by the FDA in H1 2017.

The company has an established financing plan in place for a supporting trial, which is consistent with FDA guidance. Current cash, cash generated from sales, the financing arrangements with Bracknor and Sitra, combined with the recent strategic changes in the organisation, are estimated to finance the Company until the beginning of financial year 2018.

Commenting on the announcement, Martin Jamieson, Chairman of the Board and CEO, said: "I'm delighted to have had such a constructive meeting with FDA. We are clear on our therapy strategy and I look forward to a positive outcome to our supplementary trial."

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 chronic neuropathic pain, 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