# Nexstim

### Impressive New Study Results Suggest Potential New Therapeutic Use for Nexstim SmartFocus® nTMS in Postsurgical Rehabilitation of Paresis

### Press release, Helsinki, 17 May 2021 at 10:30 AM (EEST)

Nexstim Plc (NXTMH:HEX, NXTMS:STO) ("Nexstim" or "Company") announces that a new study published in *Brain Stimulation* in May reports that the therapeutic use of Nexstim navigated repetitive transcranial magnetic stimulation (nrTMS) significantly improved outcomes for glioma patients suffering from post-surgical paresis. The study suggests that patients who suffer from a severe decline in hand function after brain tumor surgery can be treated post-operatively for 7 days with 15 minutes of nrTMS plus 30 minutes of physiotherapy per day.

The study "<u>Navigated repetitive transcranial magnetic stimulation improves the outcome of</u> <u>postsurgical paresis in glioma patients – A randomized, double-blinded trial</u>", using Nexstim's NBS System with SmartFocus<sup>®</sup> nTMS, was published by a neurosurgical team at the Technical University of Munich (TUM) in Germany (1).

This randomized, sham-controlled trial reported the use of nrTMS to treat 19 glioma patients (14 nrTMS group, 5 sham group) with severe post-surgical paresis. Patients received 15 minutes of either active or sham nrTMS treatment followed by 30 minutes of intense task-oriented physical therapy for seven consecutive days after surgery. Treatment targeted the non-damaged side of the brain, opposite the area of paresis, aiming to reduce interhemispheric inhibitory signals and facilitate the recovery of function by the lesioned brain. The primary outcome measure of the trial was change on the Fugl-Meyer Assessment (FMA) scale from start of therapy to 3 months after end of treatment.

In the trial the use of active post-operative nrTMS led to a mean increase of 31.9 points [95% confidence interval CI 22.6, 41.25] on the FMA, compared to an increase of 4.2 points [95%CI -4.14, 12.54] for the sham-controlled group (p=0.001 for statistical significance between trial arms). The increase on FMA of 12 of the 14 patients receiving active nrTMS exceeded the level of minimal clinically important difference (MCID) of 10 points defined for the study population with a number needed to treat of 2.19.

According to the publication the study was stopped early as an interim analysis demonstrated statistically significant differences between treatment arms with sufficient power, favoring active nrTMS, particularly for the primary outcome measure.

The Fugl-Meyer Assessment was originally designed to determine the severity of motor impairments in patients following a stroke. The scale ranges from 0 to 66 with higher scores indicating better function. Author Dr. Sandro Krieg comments, "the average gain of improvement in the study means for the patients the difference between a moving but uncontrollable hand to an arm and hand which can be used during daily life."

The impressive result of this new study suggests a potential new area to be explored with larger trials. According to Dr. Krieg, this approach should also be investigated for further pathologies of neuronal damage.

Mikko Karvinen, CEO of Nexstim, commented: "We are excited about the promising results of this well-designed, sham-controlled trial. We are committed to helping neurosurgeons reduce post-

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### operative deficits with our NBS System for motor and language mapping. We are pleased to know we may also play a future role in the post-operative care of patients."

1) Ille S, Kelm A, Schroeder A, Albers LE, Negwer C, Butenschoen VM, Sollmann N, Picht T, Vajkoczy P, Meyer B, Krieg SM, Navigated repetitive transcranial magnetic stimulation improves the outcome of postsurgical paresis in glioma patients – A randomized, double-blinded trial, Brain Stimulation (2021), doi: https://doi.org/10.1016/j.brs.2021.04.026.

Nexstim NexSpeech<sup>®</sup>, when used together with the NBS System 5, is indicated for non-invasive localization of cortical areas that do not contain essential speech function. NexSpeech<sup>®</sup> provides information that may be used in pre-surgical planning in patients undergoing brain surgery. Intra-operatively, the localization information provided by NexSpeech<sup>®</sup> is intended to be verified by direct cortical stimulation. The Nexstim NBS System 5 and NBS System 5 with NexSpeech<sup>®</sup> are not intended to be used during a surgical procedure. The Nexstim NBS System 5 and NBS System 5 with NexSpeech<sup>®</sup> are intended to be used by trained clinical professionals.

#### Further information is available on the website www.nexstim.com, or by contacting:

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#### About Nexstim Plc

Nexstim is a Finnish, globally operating medical technology company. Our mission is to enable personalized and effective therapies and diagnostics for challenging brain diseases and disorders.

Nexstim has developed a world-leading non-invasive brain stimulation technology called SmartFocus<sup>®</sup>. It is a navigated transcranial magnetic stimulation (nTMS) technology with highly sophisticated 3D navigation providing accurate and personalized targeting of the TMS to the specific area of the brain.

SmartFocus<sup>®</sup> technology is used in Nexstim's proprietary Navigated Brain Therapy (NBT<sup>®</sup>) system, which is FDA cleared for marketing and commercial distribution for the treatment of major depressive disorder (MDD) in the United States. In Europe, the NBT<sup>®</sup> system is CE marked for the treatment of major depression and chronic neuropathic pain.

In addition, Nexstim is commercializing its SmartFocus<sup>®</sup> based Navigated Brain Stimulation (NBS) system for diagnostic applications. The NBS system is the only FDA cleared and CE marked navigated TMS system for pre-surgical mapping of the speech and motor cortices of the brain. Nexstim shares are listed on the Nasdaq First North Growth Market Finland and Nasdaq First North Growth Market Sweden.

For more information please visit <u>www.nexstim.com</u>