Nexstim

Promising results from severe depression pilot study

3 March 2021

- Nexstim has released a summary of the results from the pilot study on the use of accelerated iTBS protocol in treating severe depression at Kuopio University Hospital. This investigator-led trial uses Nexstim's SmartFocus nTMS system with an accelerated iTBS protocol, with the results comparing the responses of 10 patients on a regimen of multiple daily sessions over one week against those seen in 10 patients undertaking conventional TMS.
- All 10 accelerated iTBS (intermittent theta burst stimulation) protocol patients completed their five-day treatment successfully, with seven also having completed at least five weeks of the planned 12-week follow-up. Positively, there were no discontinuations or serious adverse events.
- All 10 patients showed symptom improvement on the clinician administered Hamilton Depression Rating Scale (HAMD-17) outcome measure at the end of treatment. The mean decrease in HAMD-17 score from baseline was 37% ($p<0.001$). One patient (10%) achieved clinical remission and three (30%) a clinical response defined as >50% improvement on the measure.
- At the five-week follow-up, two out of seven patients (29%) remained in clinical remission and three (43%) maintained a clinical response compared with their baseline HAMD-17 score. At baseline, eight patients reported any history of suicidal ideation, with only one doing so at the end of treatment. The complete data, including follow-ups, will be published at a future scientific meeting.
- These positive data will guide the next study, which will focus on optimising and intensifying the treatment protocols to maximise therapeutic effects. The strength of these outcomes will determine the FDA registration strategy, which could range from a few single, larger studies to a significant, multi-centre trial. Clearly Nexstim would require additional funding to support such a trial.

Trinity Delta view: TMS (Transcranial Magnetic Stimulation) offers clear clinical and economic benefits in treating MDD (major depressive disorder). However, such treatment is limited by its long duration, typically five outpatient sessions per week over six weeks. Accelerated treatment regimens employing shorter, more intensive protocols have clear potential, with numerous additional benefits to patients, providers, and payors. Such protocols require highly accurate targeting, hence Nexstim's NBT (Navigated Brain Therapy) system is particularly well suited as the SmartFocus platform provides precise, reliable, and reproducible navigation. Further development of accelerated protocols are a key component of Nexstim's 2020-24 strategic plan, with successful outcomes in the future registrational studies opening a material, and commercially attractive, new inpatient treatment segment for NBT.

Price	€0.09
Market Cap	€41.3m
Primary exchange	Helsinki
Sector	Healthcare
Company Codes	NXTMH/NXTMS
Corporate client	Yes

Company description:

Nexstim is a targeted neuro-modulation company that has developed a proprietary navigated rTMS platform for use in diagnostics (NBS) and therapeutics (NBT). NBS is used in planning brain surgery while NBT is focused on depression and chronic pain. FDA approval for depression was given in 2017, and the focus is on its commercial roll out in the US, Europe and Asia.

Analysts

Lala Gregorek
lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori
fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Lala Gregorek lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori fgregori@trinitydelta.org
+44 (0) 20 3637 5041

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