

Nexstim

Nexstim Plc: Health Canada Grants Nexstim NBT® Medical Device License for Canada

Company announcement, Helsinki, 5 December 2019 at 11.10 am (EET)

Nexstim Plc (NXTMH:HEX, NXTMS:STO) announces that its NBT® System with SmartFocus® TMS technology has received a medical device license from Health Canada.

The medical device license allows Nexstim to start marketing and commercial distribution of the NBT® system for the treatment of Major Depressive Disorder (MDD) in Canada.

MDD is a recurrent and frequently chronic disorder with significant unmet clinical need: An estimated 10 per cent of Canadians use health services for mood and anxiety disorders annually¹. According to Statistics Canada, 1,330,510 Canadians over the age of 15 reported indicators for 'Major depression episode' in 2012.²

Stimulation of the brain through Transcranial Magnetic Stimulation (TMS) has been demonstrated to be effective in the treatment of MDD in patients who have failed pharmacologic treatment.³

Nexstim has already signed a distribution agreement with a Canadian distribution company Canadian Health Solutions, as announced earlier this year.

Martin Jamieson, CEO of Nexstim Plc, said: *"The Health Canada medical device licence for Nexstim NBT® system reinforces our strategy focused on therapy business in North America. We are confident that we are able to maximise the capacity of our unique SmartFocus® TMS technology in a market where there is a huge and growing need for treatments that can make a real difference in the battle against MDD."*

¹ Mood and Anxiety Disorders in Canada, 2016 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5387798/>

² 2012 Canadian Community Health Survey
<https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1310046501 >

³ O'Reardon et al. Efficacy and safety of transcranial magnetic stimulation in the acute treatment of major depression: a multisite randomized controlled trial. *Biol Psychiatry* 2007 Dec 1; 62(11)
<https://www.ncbi.nlm.nih.gov/pubmed/17573044>

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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®. 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® technology is used in Nexstim's proprietary Navigated Brain Therapy (NBT®) 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® system is CE marked for the treatment of major depression and chronic neuropathic pain.

In addition, Nexstim is commercializing its SmartFocus® 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 www.nexstim.com