Press Release
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BrainCool AB (publ) receives "Breakthrough Device" classification for new stroke therapy from FDA

BrainCool AB (publ) has been notified that the US Food and Drug Administration (FDA) has granted a "**Breakthrough Device**" designation for BrainCool´s product RhinoChill for early cooling of stroke patients receiving thrombectomy treatment.

The Breakthrough Devices program by the FDA is designed as a "fast-track program" aimed at expediting the development and approval of novel medical devices that have the potential to significantly improve the treatment or diagnosis of life-threatening diseases.

The background is the company's EU-funded first clinical study - Combination of Targeted temperature management and Thrombectomy after acute Ischemic Stroke (COTTIS). COTTIS was a pilot study, presented in the autumn of 2022 and attracted great international attention. It showed clearly positive results in thrombectomy treatment of stroke in combination with cooling with RhinoChill®. Cottis 1 included 22 patients and evaluated safety and suitability. The results also included strong data for survival with good or complete neurological function after three months. [1]

BrainCool subsequently initiated a large follow-up randomized study of a total of 400 patients, Cottis 2. Through this project, the FDA offers priority review and guidance throughout the De Novo process, placing particular emphasis on obtaining a medical indication for stroke. To qualify for Breakthrough classification, it is also required to conduct a randomized clinical trial. The clinical outcomes of COTTIS 2 will serve as the foundation for a new medical indication and a market approval of the treatment with RhinoChill. This is fully in line with the company's EU strategy. [1]

CEO Martin Waleij comments:
- “This is an important milestone for the implementation of the new stroke therapy with the RhinoChill® system. This represents a substantial potential for BrainCool in terms of both revenue and impact on the market.”

The success of Cottis 2 has the potential to open possibilities for a completely novel treatment approach and introduce a new medical indication for patients who have experienced a stroke. This area has in past seen limited advancements in terms of new treatment options reaching the market, making it particularly significant. Globally, stroke is the leading cause of mortality and disability with significant economic impact. The total direct and indirect costs of stroke in the United States are estimated to reach $140 billion by 2030. The annual economic costs in Europe are estimated at €45 billion.

The medical market using trombectomy in neurology is currently estimated to SEK 7 billion and it is expected to grow to SEK 11 billion by 2030. [2] Given the objective of the Cottis 2 study, to show as big improvement in improved survival with good neurological outcome, as thrombectomy has previously shown, it is reasonable to expect a similar market potential and size for RhinoChill® in stroke and that the market potential will grow with the expanding market for thrombectomy.

References:
1. BrainCool AB (publ): BrainCool invests in RhinoChill® System to play a central role in the treatment

of stroke with thrombectomy and that the therapy is approved as a new medical indication - BrainCool (cision.com)
2. Grandviewresearch.com/industry-analysis/neurothrombectomy-devices-market

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About Us
BrainCool AB (publ) is an innovative medical device company that develops, markets, and sells leading medical cooling systems for indications and areas with significant medical benefits within the healthcare sector. The company focuses on two business segments, Brain Cooling and Oncology. BrainCool AB (publ) is based in Lund, Sweden, and its share is listed on Nasdaq First North Growth Market, named “BRAIN”.
Eminova Fondkommission AB is the company’s Certified Adviser.

Attachments
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