Press Release
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BrainCool AB (publ): BrainCool launches a new commercialization strategy for its breakthrough product Cooral ®System aiming for reimbursement in the U.S

BrainCool AB launches a new commercialization strategy in the U.S for the new cryotherapy product Cooral ®System supporting patients undergoing treatment for cancer.

- Braincool has now created a strategy for reimbursement in the U.S. The strategy includes a clinical trial in the U.S.
- In October 2022 Cooral® System obtained De Novo 510 k approval with a Breakthrough designation from FDA in the U.S.
- Cooral® System is one of very few Breakthrough devices which has obtained FDA approval.
- Significant revenue potential via expected automatic reimbursement for break-through products.
- Approximately 500,000 patients per year are affected by oral mucositis during cancer treatment in the US and Cooral® System can create potential cost savings of 40,000 USD per patient with oral mucositis.

Cooral ® Systems is one of the first breakthrough medical products that has obtained market approval in the U.S. If the strategy is successful, it will create substantial value not only for the patients but also for BrainCool and its shareholders. In parallel, a global marketing strategy will be developed.

BrainCool has developed Cooral ®Systems over the past few years to address the severe problem with oral mucositis (OM) that may affect patients under cancer treatment. A large -multi-clinical study demonstrated the efficacy of the Cooral device to reduce the incidence of OM in patients undergoing chemotherapy and in October 2022 Cooral® System obtained De Novo 510 k approval with a Breakthrough designation from FDA in the U.S. The approval applies for all chemotherapy regimens that may lead to OM and is not restricted to any specific chemo agent or cancer indication.

There is a strong support for using the new cryotherapy product preventing and mitigating OM from major oncology societies in the US such as the International Society of Oral Oncology, American Society of Clinical Oncology, and the Oncology Nursing Society.

The healthcare cost related to OM is very high. On an average, it is estimated to roughly 25,000 USD per patient with around half a million patients treated annually in the U.S according to a published study. Thus, there is a strong proposition to alleviate and cure OM, both from a health economic point and less pain and strain for the patient and even lethal outcomes.

BrainCool has decided to pursue a step-by-step strategy starting in the U.S. In view of the substantial

cost related to OM and the potential savings in using devices mitigating OM, BrainCool will seek the pathway of a reimbursement strategy for Cooral ®Systems. That will broaden the market with more hospitals using Cooral ®Systems against OM and create a more stable pricing of the product in the US as well as worldwide.

There are several reimbursement systems in the U.S – Medicare, Medicaid, Government Programs and Commercial Insurers. As of today, there is strong support from the Biden administration, FDA and Medicare for an automatic reimbursement under a program called TCET for break-through products such as Cooral ®Systems.

Automatic reimbursement would be very beneficial for BrainCool and Cooral ®Systems as it does not require a U.S-based clinical trial. However, if implemented the TCET rule will most likely will be capped in time to 3 – 4 years. Thus, without a dedicated U.S trial the project might risk losing the reimbursement coverage in the long term. In addition, BrainCool will in the long-term benefit in seeking to establish reimbursement framework also from the private insurance sector.
The key reimbursement fundamentals are coding, coverage, and payment. Coding is used to identify what procedure or device is used on a submitted claim to a third-party payer. Third party payers determine coverage, based on whether the procedure or device is medically necessary or reasonable and necessary to treat a condition; and payment is given to a provider for a procedure or device.

To underpin the fundamentals, BrainCool has to establish a robust U.S reimbursement structure with a randomized, controlled trial with U.S patients only. This will be designed to provide valuable health economic data to support market pricing and standard reimbursement of Cooral ®System from both private insurers and government insurers such as Centers for Medicare and Medicaid Services (CMS).

BrainCool will address a niche market in the U.S clinical trial to ensure cost efficiency in attaining reimbursement. The focus is on patients affected by lymphoma that are also treated with stem cell transplants. In the U.S, there are 350 stem cell transplant centers treating 20 000 patients annually. The trial will encompass 80-100 patients with the first patient enrolled in the first quarter of 2024. The study is expected to be completed in 2025.

In 2023 BrainCool will prepare for the study by identifying and enrolling 3-5 stem cell centers in the trial, obtaining a code CPT 3 and get an approval of the study among the most important actions.
The action plan for 2023 through 2025:

2023

- Establish usage and reference of the product at leading U.S sites.
- Apply for relevant codes from the American Medical Association.
- Define and establish clinical trials with the objective of obtaining high coverage. The clinical trials will be reconciled with both Medicare and private insurers ahead of starting the clinical trial in 2024. The clinical trial will focus on lymphoma patients where Cooral ®System have shown strong data in a sub-group in the Nordic clinical trial.

2024

- Start recruitment to the clinical trial of 80 – 100 patients.

2025

- Negotiate pricing with Medicare and private insurers ahead of launch of the product.

A cost-benefit analysis of the investment shows a very rewarding and favorable outcome for BrainCool. The average cost for OM in stem cell patients is estimated to 70,000 USD. By reducing the incidence of OM, cost savings may amount to 40,000 USD. That would imply a total saving of 800 million dollars based on 20 000 stem cell patients annually. And this is just a small but an important part of the market. A total of roughly 500,000 patients in the U.S are affected by OM to a varying extent when under some cancer treatment.

CEO of BrainCool Martin Waleij comments:

- "We believe our value proposition for the Cooral ®System is unique and compelling, particularly in light of the major unmet medical needs that our products address globally, our high margin business model and the validation of our technology in Scandinavia. With approval and an established reimbursement system we expect a rapid adoption under current cancer treatments payment bundles alternatively with product specific only reimbursement. The U.S is the largest medical device market in the world, with the potential to significantly accelerate our sales growth and profitability. The U.S reimbursement strategy would also be beneficial for marketing in both the EU and Japan market going forward."

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About Us
About BrainCool AB (publ)
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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