BrainCool AB: BrainCool AB (publ): Pressmeddelande om Breakthrough Designation för Cooral® System i USA

Nedan bifogas ett pressmeddelande (utan MAR-etikett) som distribuerades idag i USA kl 07.00 EST, för att ge information om Cooral® System, samt bolagets erhållna milstolpar ”breakthrough designation” och nationell försäkringsersättning för produkten.

Informationen är en del av en nyhets- och mediakampanj för att öka medvetenheten kring problemet med Oral Mukosit (OM), sprida information om betydelsen och det allvarliga problemet med OM i den amerikanska sjukvården, samt möjligheterna att motverka denna mycket smärtsamma åkomma med kylning och produkten Cooral® System i avvaktan på ett marknadsgodkännande för produkten i USA.

Det regulatoriska pressmeddelandet med MAR-etikett distribuerades i Sverige: 2021-01-31 16:57:14vid kl 09.35 Nyhets artikel | Spotlight (spotlightstockmarket.com)

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BrainCool AB (publ) Receives FDA “Breakthrough Device” Designation for Cooral® System for Prevention of Oral Mucositis

Recent Medicare Reimbursement Ruling Provides an Additional Boost in Paving the Way for Elimination of One of the Severest Side-Effects of Cancer Treatment

LUND, Sweden—February 11, 2021—BrainCool AB (publ), a Swedish medical device innovator, and a world leader in medical cooling technology for therapeutic hypothermia (brain cooling) and oncology, announced today that the U.S. Food and Drug Administration (FDA) has granted “**Breakthrough Device” Designation** for the **Cooral® System**, for prevention of Oral Mucositis.

The FDA Breakthrough Devices Program, implemented by the FDA in 2018, replaces other fast track programs, and is intended to increase delivery of innovative medical devices that “*provide for more effective treatment or diagnosis of life-threatening, or irreversibly debilitating diseases.*” With this designation, the FDA will provide priority review and feedback throughout the final stages market clearance through a De Novo 510 k process, and continued support as the device enters the market in the United States.

In addition to “Breakthrough Device” Designation, the Cooral® System will benefit significantly from recent Centers for Medicare & Medicaid Services (CMS) reimbursement changes that ensure coverage of medical devices designated as breakthrough by the FDA. The Medicare Coverage of Innovative Technology (MCIT) (CMS-3372-P) rule, which was finalized on January 12, 2021, stipulates that national Medicare coverage for devices with “Breakthrough Designation” begins on the date of FDA market authorization and continues for four years.

"*This is a significant milestone for the Cooral® System,*" said Martin Waleij CEO BrainCool AB (publ). “*Not only does this ‘Breakthrough Designation’ safeguard a faster and smoother regulatory process as we enter the U.S. market, the new CMS reimbursement ruling is a vital mechanism for getting the device into clinical practice where it can actively benefit patients without further delay.*"

The Cooral® System, CE marked in June 2020 as an invasive medical device in the EU, has shown statistically significant evidence of its safety and effectiveness in clinical trials. A study presented at a late breaking session during the 2020 European Society for Medical Oncology’s Virtual Meeting in September, is expected to be published in a major scientific journal this spring.

As part of its application for FDA Breakthrough Designation, BrainCool AB (publ) was able to present already completed clinical results from the Nordic multi-center study assessing the safety and effectiveness of the Cooral® System and showing significant evidence for prevention of OM.

“*We are confident that positive outcomes from recent clinical studies showing the Cooral System’s ability to prevent oral mucositis were a major factor in winning this FDA Breakthrough Designation.*” Added Waleij. “*The double benefit of this Breakthrough Designation and CMS reimbursement decision represent a significant advance in cancer treatment options and*

the relief of patient suffering."

"Intra-oral cooling to prevent or mitigate oral mucositis represents an important, safe, and effective technology for selected cohorts of oncology patients," said Douglas E. Peterson,D.M.D., Ph.D., a consultant to BrainCool. "Based on my several decades of research and clinical experience relative to oral mucositis caused by cancer therapies, reduction of the severe pain and ulceration associated with the condition is key, especially for patients on aggressive treatment schedules for whom delays due to oral mucositis may be life-threatening."

"Oncologists all over the world are in need of a better cooling method to prevent Oral Mucositis and thus improving the quality of life for the patients, said Roger Henriksson, MD, PhD, Senior Professor, University in Umeå. "Cooling is a well-known method to prevent this chemo-induced side effect, but it is only limitedly applied in clinics because using ice water is painful for the patient and poorly tolerated during the entire treatment time. Risk of infection can also be a deterrent. The Cooral® System is an important step forward and much-needed technology."

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About Oral Mucositis (OM)

OM is a highly significant and sometimes dose-limiting condition that has been reported as the single most-debilitating complication of cancer therapy. OM can be present in combination with a variety of debilitating symptoms that may compromise the ability of patients to maintain oral hygiene practices. For example, intractable oral pain, which may lead to an increased need for analgesics and, on occasions, opioids that are administered intravenously. OM is further associated with undernourishment, weight loss, the use of feeding tubes or total parenteral nutrition, and impaired quality of life, and it can represent a portal of entry for systemic infections that can lead to sepsis and death. Taken together, these symptoms, along with their related sequelae, can result in hospitalization and may incur increased costs for healthcare systems.

Files for Download:

Studies: http://cooral.eu/clinical-om/#

Oral Mucositis Background: http://cooral.eu/the-pathobiology-2/

About BrainCool AB (publ)

Based in Lund, Sweden, Europe, BrainCool AB (publ) (Spotlight markets BRAIN) is a publicly traded medical device company focused on next-generation temperature management systems. The company has two business units, braincooling, with the two CE marked products BrainCool System and RhinoChill, and in oncology with the Cooral® System. BrainCool, Inc, the U.S. subsidiary of BrainCool AB, is based in Annapolis Maryland. The IQool® System, which received FDA 510(k) Clearance in 2018, was the first BrainCool product to be marketed in the United States.

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För mer information

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Om BrainCool AB (publ)

BrainCool AB (publ) är ett innovativt medicinteknikföretag som utvecklar, marknadsför och säljer ledande medicinska kylningssystem för indikationer och områden med betydande medicinska mervärden inom sjukvården. Bolaget fokuserar på två affärsområden, Brain Cooling och Onkologi. BrainCool AB (publ) har sitt säte i Lund. Aktien är noterad på Spotlight Stock Market.