



## **BrainCool AB (publ): Pressmeddelande om Cooral® Studien i USA**

Nedan bifogas ett pressmeddelande (utan MAR-etikett) som distribuerades idag i USA kl 08.00 EST, för att ge information om Cooral® System och den kliniska studien som idag presenterades på ESMO-mötet.

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 kyllning och produkten Cooral® System i avvaktan på ett marknadsgodkännande för produkten i USA.

Det regulatoriska pressmeddelandet med MAR-etikett distribuerades i Sverige vid kl 09.35  
<https://news.cision.com/se/braincool/r/braincool-ab--publ--kliniskt-och-statistiskt-signifika-resultat-for-att-motverka-oral-mukosit-med,c3196290>

### **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 kyllningssystem 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.*

**FOR IMMEDIATE RELEASE**

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## **BrainCool Announces Statistically Significant Late-Breaking Clinical Data at ESMO Virtual Congress 2020**

***Cooral® System Intra-Oral Cooling Device Prevents Oral Mucositis (OM)***

**A New Standard is Set for Preventing One of the Severest Side-Effects of Cancer Treatment**

**LUND, Sweden—September 18, 2020**—[BrainCool AB](#), a Swedish medical device innovator, and a world leader in medical cooling technology for therapeutic hypothermia (brain cooling) and oncology, today announced late-breaking clinical results of the Cooral® System, a novel cooling device for the prevention of Oral Mucositis (OM), at the **European Society for Medical Oncology (ESMO) Virtual Congress 2020**.

Data was collected from a Nordic multi-center pivotal trial led by Karolinska University Hospital, Stockholm, that enrolled 182 patients with multiple myeloma or lymphoma who were scheduled to receive high-dose chemotherapy prior to hematopoietic stem cell transplantation. The abstract was presented at ESMO by [Java Walladbegi, PhD](#), Oral Medicine, Department of Oral Medicine & Pathology, Institute of Odontology at The Sahlgrenska Academy, University of Gothenburg, Sweden. Dr. Walladbegi was project manager for the blinded, randomized investigation, which compared the efficacy of ice chips (IC) and an intra-oral cooling device (ICD; Cooral®) for cryoprevention of OM.

Results from the randomized trial proved that the Cooral® System was as effective as IC in terms of cryoprevention, with severe OM occurring in fewer than 10% of the cases tested. For patients with lymphoma, use of the Cooral® System showed vastly improved prevention of OM and was significantly more effective when compared to the conventional method with IC [Oral Mucositis Assessment Scale (OMAS) mean total 1.77 vs 3.08;  $p = 0.047$ ]. This finding is particularly notable because lymphoma patients are treated with longer courses of chemotherapy, making severe OM a life-threatening inevitability. As for patient-reported tolerability, both diagnostic groups (myeloma and lymphoma), reported a statistically significant higher degree of tolerability when Cooral® was used as compared with IC [ $p = 0.020$ ].

“This is a major breakthrough in patient-centered cancer care and treatment,” said Martin Waleij, CEO of BrainCool. “Not only was the Cooral® System shown to be safer and more feasible from the standpoint of infection control and comfort, our study shows that its use actually prevents OM occurrence. For patients faced with treatment times of up to six hours or more, that is a truly life-changing difference.”

In addition to cancer care improvements, the study indicates potential economic benefits as well. Costs for patients with severe OM in conjunction with stem cell transplantation have been estimated at more than \$70,000 per patient. The data presented at ESMO are a clear indication that most of these healthcare costs can be prevented with use of the Cooral® System.

Presentation of this data at ESMO paves the way for market introduction of the Cooral® System in the EU, following market clearance in early June 2020 as a class 2 invasive medical device. The device was CE marked for the EU / ESS markets as an invasive medical device this past June, and BrainCool is currently conducting a De Novo 510(k) process to obtain market clearance in the U.S.

The Cooral® System features a disposable, thermostatically controlled intra-oral device that comprises closed conduits with continuously circulating water to evenly distribute the hypothermic medium to the oral mucosa. As the hypothermic medium gradually reaches a steady temperature, that temperature is consistently controlled and maintained in the oral mucosa, which in turn leads to reduced blood flow and exposure of tissue to chemotherapeutic agents—thus preventing soreness, erythema and painful ulcerative lesions.

“Oral Mucositis is among the most painful and debilitating adverse effects of both standard and high-dose chemotherapy within the field of oncology,” said Dr. Java Walladbegi. “The data speaks for itself, and represents an important milestone in the quest to prevent this potentially lethal side-effect.”

“We are opening an important new door in cancer care and treatment,” adds Waleij. “Together with an anticipated scientific publication in early 2021, this ESMO late-breaking presentation marks the international launch of a groundbreaking improvement in cancer care that significantly improves quality of life for patients, and dramatically reduces the cost to deliver it.”

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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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