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BrainCool Ab (publ) Completes Patient Recruitment in a Scandinavian Pivotal Trial for FDA Clearance of Oral Mucositis Treatment in the United States

Cooral® System on Track with U.S. De Novo 510 k Process for Market Registration in the U.S.

Intra-Oral Cooling Device is Tested in 180 Patients to Eliminate Oral Mucositis (OM), One of the Severest Side-Effects of Radiology and Chemotherapy for Blood, Bone or Solid Tumor Cancer Treatment

LUND, Sweden—February 11, 2020—[BrainCool AB](#), a Swedish medical device innovator, and a world leader in medical cooling technology for therapeutic hypothermia (brain cooling) and oncology, is pleased to announce that it has completed patient recruitment in the Scandinavian multi-center pivotal trial of 180 patients to investigate the patented Cooral® System for prevention of Oral Mucositis (OM), one of the most debilitating side-effects of both standard and high-dose chemotherapeutic oncology treatments.

In the United States (U.S.), BrainCool is conducting a De Novo 510 k regulatory process, with the aim of obtaining product and market clearance for the Cooral® System in the U.S. by the Food and Drug Administration (FDA). The De Novo process was introduced by the FDA for instances where a device is novel and there is therefore no suitable predicate device to support a standard 510(k) submission. To qualify for the De Novo pathway, the new device must also present no more than moderate risk.

BrainCool has been granted FDA “Expedited Access Pathway” (EAP) status and will be given priority review for the Cooral® System. EAP projects address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions that are subject to premarket approval applications (PMA), or are eligible for *de novo* requests.

“With full patient recruitment for our pivotal trial, we are opening an important new door in cancer care and treatment,” said Martin Waleij, CEO BrainCool AB. “Conclusive validation that cryotherapeutic intervention with the Cooral® System can safely and effectively prevent the excruciating side-effects of oral mucositis is not just a major medical milestone, it’s actually a matter of life and death.”

The Cooral® System intra-oral cooling device includes a disposable and thermostatically controlled mouthpiece that fills with a hypothermic liquid, which circulates through the system’s channels. As the coolant gradually reaches and maintains a consistently controlled temperature, the system reduces blood flow and exposure of tissue to radiation or chemotherapeutic agents, thus preventing adverse mucosal erythema and ulcerative reactions.

Details of the Clinical Study and the Expedited Access Pathway (EAP)

The Nordic clinical trial of 180 patients has been selected by the U.S. FDA as part of the De Novo 510 process for obtaining market clearance in the U.S. Patients have been recruited over a period of two years across five important medical centers, including the lead site, **Karolinska Universitetsjukhuset in Stockholm**, Sweden.

Clinical data from the Nordic trial will be applicable for FDA submission. BrainCool is currently working on a module-based application wherein the first two modules contain quality routines for product development and manufacturing. The third and final module will contain clinical data from the completed Pivotal trial and will be submitted as soon as the results are available. Thereafter FDA will review the documentation and decide on a product and market approval.

About Oral Mucositis (OM)

Oral Mucositis significantly affects the quality of life for cancer patients in terms of pain, ability to eat, swallow and talk. The symptoms are often of such severity that they result in an interruption and curtailment of therapy. OM can also lead to dose reduction of the cancer therapy and treatment delays. In many cases these patients require hospitalization. OM has a direct and significant effect on the duration of disease remission and cure rates due to its dose-limiting toxicity. In some cases, risk for infection threatens survival, and there is a significant impact on quality of life and cost of care. The presence of OM is a major driver of health-care cost. Read more: <http://cooral.eu/the-pathobiology/>.

Files for Download:

Product Images: <https://bit.ly/2UKgfoL>

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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