



BrainCool AB (publ) has completed the recruitment in the Nordic clinical study with Cooral® System to prevent oral mucositis (OM)

The recruitment to the Nordic study to prevent oral mucositis is now completed. The study is a controlled, randomized Nordic study of 180 patients treated with powerful cytostatic therapy due to malignant blood disorders. In the study, BrainCool's product Cooral® System was evaluated to prevent troublesome mucosal damage in the oral cavity and pharynx (oral mucositis, OM).

“The completed recruitment is an important milestone for BrainCool and Cooral® System. I am extremely grateful for the team's hard work at the clinics”- says Martin Waleij, CEO of BrainCool AB.

The analysis of the study results as well as preparation for publication and presentation is expected to be ready during the first quarter of 2020. The results will initially be presented to the US FDA, as the study will form the basis of a US market approval, in a so called De Novo 510k process.

About Cooral® System and oral mucositis (OM)

Cooral® System is a medical device for the prevention of oral mucositis (OM). OM is a toxic mucosal injury that can occur after treatment with cytostatic drugs or radiation, which are common treatments of various types of cancer. Virtually all patients who undergo high-dose cytostatic treatment prior to bone marrow transplantation, nearly 80 percent of patients receiving radiation therapy to the head and neck region, and a large proportion (40-70 percent) of patients receiving cytostatic treatment within general oncology suffer from OM.

OM causes redness, burning, and ulcerations in the mucous membranes of the mouth leads to considerable pain that lowers the patient's quality of life and can in many cases require high doses of morphine. OM impedes food intake and the maintenance of good oral hygiene, which in turn can lead to nutritional deficiencies and infections. OM also risks that the tumor treatment cannot be performed in an optimal way, which reduces the possibility of a good treatment response. Given this, OM represents a serious medical risk and strain for the affected patient with impaired quality of life. The consequence of OM also entails significant cost increases, for example extended hospital stay.

The use of ice-cooling has been shown to reduce the severity and extent of OM, although clinical use is still limited due to several disadvantages. These include problems with contaminated tap water, nausea, and fluctuating cooling of the oral mucosa with great discomfort for the patient as shooting pain in the teeth. These disadvantages do not arise when using Cooral®. Despite the disadvantages of ice, MASCC, which is the international body that provides recommendations for treatment of OM, continues to recommend treatment with ice due to few alternative modalities.

CEO Martin Waleij comments;

- With regards to patients with lymphoma, Cooral® System has built up experience in cooling patients for up to six hours per day, which shows that Cooral® can be of



significant value to large groups of cancer patients during treatment where it is often only necessary to cool less than 4 hours. The global market potential for treating troublesome oral mucositis is very large. The cost of patients with severe OM, within the group of patients undergoing stem cell transplantation, has been estimated at over USD 70,000 per patient (J Natl Cancer Inst Monogr (2019) 2019 (53): lgz010). Our solution with the Cooral® System to prevent OM and thus prevent the problem, therefore also offers considerable added value in terms of health economics.

For more information

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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 Pain Management. BrainCool AB (publ) is based in Lund, Sweden, and its share is listed on Spotlight Stock Market.

This information is information that BrainCool (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out herein, on November 7, 2019.